

EXHIBIT 1

Protected Information - Jerrold R. Turner, M.D., Ph.D.

1 UNITED STATES DISTRICT COURT OF NEW JERSEY
CAMDEN DIVISION

2

3 IN RE: BENICAR (OLMESARTAN)
PRODUCTS LIABILITY LITIGATION MDL No. 2606

4 *****

5

6 SUPERIOR COURT OF NEW JERSEY
ATLANTIC COUNTY

7

8 IN RE: BENICAR (OLMESARTAN) MCL No. 299
MEDOXOMIL) LITIGATION

9 *****

10

11 ***PROTECTED INFORMATION***

12

13 VIDEOTAPED DEPOSITION OF
14 JERROLD R. TURNER, MD, PhD

15

16 Thursday, February 16th, 2017

17 9:14 a.m.

18 Held At:

19 Campbell Campbell Edwards & Conroy, PC
20 One Constitution Plaza
21 Boston, Massachusetts

22

23 REPORTED BY:

24 Maureen O'Connor Pollard, RMR, CLR, CSR

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<p>1 APPEARANCES:</p> <p>2</p> <p>3 FOR THE PLAINTIFFS:</p> <p>4 ADAM SLATER, ESQ. (By videoconference)</p> <p>5 MAZIE SLATER KATZ & FREEMAN, LLC</p> <p>6 103 Eisenhower Parkway</p> <p>7 Roseland, New Jersey 07068</p> <p>8 973-228-9898</p> <p>9 aslater@mskf.net</p> <p>10</p> <p>11 -and-</p> <p>12</p> <p>13 PETER N. FOUNDAS, ESQ.</p> <p>14 ROBINS KAPLAN, LLP</p> <p>15 800 Boylston Street</p> <p>16 Boston, Massachusetts 02199</p> <p>17 617-859-2720</p> <p>18 pfoundas@robinskaplan.com</p> <p>19 FOR THE DEFENDANT DAICCHI-SANKYO and THE</p> <p>20 DEPONENT:</p> <p>21 BRUCE R. PARKER, ESQ.</p> <p>22 VENABLE LLP</p> <p>23 750 E. Pratt Street</p> <p>24 Baltimore, Maryland 21202</p> <p>410-244-7534</p> <p>brparker@venable.com</p> <p>VIDEOGRAPHER: Christopher Coughlin</p> <p>Present via phone:</p> <p>Hilary Kelly, Esq.</p> <p>Daiichi-Sankyo</p>	<p>1</p> <p>2 9 Gallivan and Brown letter to the</p> <p>3 editor titled Olmesartan induced</p> <p>4 enterocolitis.....104</p> <p>5</p> <p>6 10 Marietta, et al article titled</p> <p>7 Drug-Induced Enteropathy.....125</p> <p>8</p> <p>9 11 Freeman article titled</p> <p>10 Drug-induced Sprue-like Intestinal</p> <p>11 Disease.....137</p> <p>12 12 Green and Cellier article titled</p> <p>13 Celiac Disease.....145</p> <p>14</p> <p>15 13 Setty, et al article titled</p> <p>16 Distinct and Synergistic</p> <p>17 Contributions of Epithelial Stress</p> <p>18 and Adaptive Immunity to Functions</p> <p>19 of Intraepithelial Killer Cells</p> <p>20 and Active Celiac Disease.....170</p> <p>21</p> <p>22 14 Marietta, et al article titled</p> <p>23 Immunopathogenesis of</p> <p>24 olmesartan-associated enteropathy....225</p> <p>15 15 Rubio-Tapia, et al article titled</p> <p>16 Severe Sprue-like Enteropathy</p> <p>17 Associated With Olmesartan.....225</p> <p>18</p> <p>19 16 Choi and McKenna article titled</p> <p>20 Olmesartan-Associated Enteropathy.</p> <p>21 A Review of Clinical and</p> <p>22 Histologic Findings.....239</p> <p>23</p> <p>24 17 Marthey, et al article titled</p> <p>Olmesartan-associated enteropathy:</p> <p>results of a national survey.....274</p> <p>20</p> <p>21 18 Kulai, et al article titled Images</p> <p>22 of the Month: Duodenal Villous</p> <p>23 Atrophy in a TTG-Negative Patient</p> <p>24 Taking Olmesartan: A Case Report</p> <p>and Review of the Literature.....280</p> <p>19 FDA Drug Safety Communication.....322</p>
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<p style="text-align: right;">Page 6</p> <p>1 JERROLD R. TURNER, MD, PhD, 2 having been first duly identified and sworn, was 3 examined and testified as follows: 4 EXAMINATION 5 BY MR. SLATER: 6 Q. Good morning, Dr. Turner. 7 A. Good morning. 8 Q. I introduced myself in a bit of a 9 flurry of activity just a few moments ago, my 10 name is Adam Slater, I'm going to take your 11 deposition now in the Benicar (Olmesartan) 12 Product Liability Litigation. 13 Do you understand that's what we're 14 going to do today? 15 A. Yes. 16 Q. My understanding is you have had your 17 deposition taken previously as an expert witness 18 in other litigation, correct? 19 A. Yes, I have. 20 Q. You understand you're now under oath 21 and must tell the truth in response to every 22 question I ask you? 23 A. Yes. 24 Q. If I ask you a question that doesn't</p>	<p style="text-align: right;">Page 8</p> <p>1 Do you see that? 2 A. Yes, I do. 3 (Whereupon, Turner Exhibit Number 1, 4 Notice to Take Videotaped Oral 5 Deposition, was marked for 6 identification.) 7 BY MR. SLATER: 8 Q. Have you seen that before right now? 9 A. Yesterday. 10 Q. What I'd like to do now is mark 11 Exhibit 2. We have Exhibit 2. Do you have that 12 in front of you? And Exhibit 3. 13 MR. SLATER: Give him both, please. 14 (Whereupon, Turner Exhibit Number 2, 15 Responses and Objections to 16 Plaintiffs' Notice of Oral Deposition, 17 and Number 3, 2/15/17 Letter to Adam 18 Slater from Susan Sharko, were marked 19 for identification.) 20 A. Okay. 21 BY MR. SLATER: 22 Q. Doctor, do you see Exhibit 2 and 23 Exhibit 3? 24 A. Yes, I do.</p>
<p style="text-align: right;">Page 7</p> <p>1 make sense to you for any reason, for example, I 2 mispronounce terminology, the question that 3 doesn't make medical sense to you, for whatever 4 reason, if the question doesn't make sense to 5 you, such that you cannot answer truthfully and 6 completely, you just need to tell me that, and 7 then we'll talk about what's unclear and I'll 8 try to rephrase the question. Okay? 9 A. Yes. 10 Q. Mr. Parker may object to some of my 11 questions, and if he does, just let him speak, 12 and then my expectation is in those cases, if 13 not all cases, you'll go ahead and answer the 14 question. But I'm sure you've been in 15 depositions where lawyers object to the form of 16 the question that you probably will hear several 17 times today, that's not a signal not to answer, 18 it just means he's preserving his rights for the 19 future, and then you'll go ahead and answer. 20 Do you understand that? 21 A. Yes, I do. 22 Q. Doctor, in front of you should be 23 what's been marked as Exhibit 1, the notice of 24 deposition.</p>	<p style="text-align: right;">Page 9</p> <p>1 Q. Exhibit 3 is a letter I received 2 yesterday enclosing the response and objections 3 to our deposition notice, which is Exhibit 2. 4 Do you see that? 5 A. Yes, I do. 6 Q. Have you seen Exhibit 2 before right 7 now? 8 A. No. 9 Q. Have you seen Exhibit 3, which is the 10 cover letter, have you ever seen that before 11 right now? 12 A. No. 13 Q. Let's go through Exhibit 2 for a few 14 minutes, okay? 15 A. Okay. 16 Q. The first request was for "Copies of 17 all invoices for work performed in connection 18 with Benicar/Olmesartan whether for litigation 19 or non-litigation related consulting, or 20 litigation related work." 21 Do you see that request? 22 A. Yes, I do. 23 Q. Okay. Now, I'd like you to look at 24 Exhibit 6, please?</p>

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<p style="text-align: right;">Page 10</p> <p>1 (Whereupon, Turner Exhibit Number 6, 2 Copies of three invoices, was marked 3 for identification.) 4 MR. SLATER: Maureen, you can just 5 give him all the exhibits. There's no reason 6 not to just give it to him. I don't mind. 7 Let's make it easier. 8 BY MR. SLATER: 9 Q. Doctor, what is Exhibit 6? 10 A. Exhibit 6 is invoices. 11 Q. Is Exhibit 6 the documents you 12 produced in response to request number 1 in the 13 deposition notice? 14 A. Yes, but there's a lot of duplications 15 in here, I think. 16 MR. PARKER: I think there are two 17 sets. 18 A. At least two sets. 19 BY MR. SLATER: 20 Q. It should be three pages, correct? 21 A. I think there's only three invoices 22 total, right. 23 Q. Let's fix it. Let's make it so that 24 Exhibit 6 is the three pages it should be, and</p>	<p style="text-align: right;">Page 12</p> <p>1 Q. Did you prepare for this deposition? 2 A. Yes, I did. 3 Q. How much -- all right. 4 How much time have you spent since 5 October 9th that has not been placed into one of 6 these invoices? 7 A. I'm guessing somewhere between 100 and 8 200 hours. 9 Q. That's a pretty broad range. Let's 10 break it down. 11 How much time did you spend preparing 12 your report? That was one of the categories you 13 gave me. 14 A. I couldn't tell you. 15 Q. You have no idea? 16 A. I haven't gone back through notes. 17 That's why I gave you a range. I have not gone 18 back in billing. 19 Q. Do you have notes that reflect the 20 time you've spent that has not yet been placed 21 into invoices? 22 A. I have my calendar, my overall 23 calendar. 24 Q. Where is that?</p>
<p style="text-align: right;">Page 11</p> <p>1 that's it. 2 A. Just the first three is fine. 3 Q. Okay. Doctor, Exhibit 6, that's a 4 three page document now which is invoices dated 5 April 23, 2016, May 24, 2016, and October 9, 6 2016. Are those the invoices you produced in 7 response to request number 1? 8 A. Yes. 9 Q. Does that represent all of the time 10 that you have spent working on this litigation? 11 A. No. 12 Q. Tell me what time is not reflected on 13 those invoices. 14 A. Anything after October 9th. 15 Q. Tell me what occurred after October 9. 16 Tell me how much time, and what was done. 17 A. I can tell you that that's when I 18 prepared all the reports that I've worked on. 19 I've had several meetings with Mr. Parker, 20 several phone calls with Mr. Parker. 21 Q. Anything else that you've done since 22 October 9 up until the time we sat down and 23 started this deposition? 24 A. I think in broad terms that covers it.</p>	<p style="text-align: right;">Page 13</p> <p>1 A. It's at home on my computer. 2 Q. And on that calendar, did you document 3 the amount of time that you spent on this case 4 since October 9th? 5 A. I noted blocks of time I spent, yes. 6 Q. And did you label what you spent time 7 doing? 8 A. No. 9 Q. What were you going to do when you 10 invoiced them, just arbitrarily do categories, 11 or do you have a record of what you actually did 12 during those time blocks? 13 A. I don't have a specific record in each 14 time block. I do think I can generally estimate 15 when I look at that how much time was spent on 16 which report. 17 Q. Do you have access to your calendar 18 from where you are right now? 19 A. No, I do not. 20 Q. Look at request number 2, please, on 21 the deposition notice we marked -- well, look at 22 Number 2 actually. Okay? That's with the 23 response. Request number 2 was "Copies of any 24 notes, i.e. written or electronic, reflecting</p>

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<p style="text-align: right;">Page 14</p> <p>1 consulting or litigation work that has not been 2 documented in invoices as of the date of the 3 deposition." 4 Do you see that request? 5 A. I do. 6 Q. And responsive to that would be the 7 entries on your calendar that you keep on your 8 computer at home, correct? 9 A. I don't think there's a good way to 10 separate those. 11 Q. Sir, I move to strike. I didn't ask 12 you. 13 The question is, the time -- rephrase. 14 The electronic notes of the time that 15 you have spent that has not yet been documented 16 in the invoices you produced as Exhibit 6 is on 17 your calendar on your computer at home, correct? 18 A. I don't think that's right. I think 19 it asks for consulting or litigation work. 20 Q. Do you -- you don't -- rephrase. 21 You don't consider the work to prepare 22 the report, have meetings with Mr. Parker, phone 23 calls with Mr. Parker, and prepare for this 24 deposition to be consulting or litigation work?</p>	<p style="text-align: right;">Page 16</p> <p>1 those times and at least tell me what the times 2 are that are documented? 3 A. Not on my home computer, no. 4 Q. What's the amount that you are billing 5 in terms of an hourly rate for the work you're 6 doing in this case? 7 A. \$500 per hour. 8 Q. Does that include deposition time? 9 A. That includes everything. 10 Q. It includes trial testimony or hearing 11 testimony if you go to court? 12 A. Yes. 13 Q. You estimated that you have 100 to 14 200 hours that you have not yet invoiced since 15 October 9, 2016, correct? 16 A. Correct. 17 Q. When are you going to invoice for that 18 time? 19 A. Certainly by the end of March. 20 Quarterly. 21 Q. In looking at your invoices, the first 22 one dated April 23, 2016 documents a three and a 23 half hour document review and phone call with 24 Mr. Babington. Is that the first time that you</p>
<p style="text-align: right;">Page 15</p> <p>1 A. Of course I do. 2 Q. Okay. So that time is documented on 3 your electronic calendar, and you did not 4 produce copies of that today, correct? 5 A. As I said, I don't think -- I don't 6 think an annotation in my calendar that says -- 7 you know, blocks out the morning for working on 8 this case represents work. It's just a space 9 holder in my calendar so that I don't get caught 10 up in other things there. 11 Q. Sir, those notes in your calendar 12 document that you did consulting or litigation 13 work that you have not put into an invoice yet, 14 correct? 15 A. They document time that I spent, yes. 16 Q. You didn't produce that today, 17 correct? 18 A. No. 19 Q. I'm going to ask, is there a way to 20 get that to us before this deposition ends 21 today? 22 A. I don't think so. 23 Q. You can't electronically get into your 24 calendar from where you are remotely and look at</p>	<p style="text-align: right;">Page 17</p> <p>1 ever did any work in connection with this 2 litigation? 3 A. Yes. 4 Q. Have you consulted for Daiichi 5 separate and apart from the litigation work and 6 litigation consulting you're doing? 7 A. No. 8 Q. When were you first contacted and 9 asked if you would review documents and speak to 10 the representatives of Daiichi in connection 11 with this litigation? 12 A. Somewhere in the few months before 13 April 23rd, 2016, actually in the -- 14 Q. It says that your first phone call was 15 March 31. 16 A. Right. I was trying to finish. 17 Q. You would have been contacted before 18 March 31, right? 19 A. You have to let me finish my answers. 20 What I was saying was, given the date 21 on it is March 31st, it would probably be 22 somewhere in the few months before that, 23 February perhaps. 24 Q. Who contacted you first?</p>

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<p style="text-align: right;">Page 18</p> <p>1 A. I believe it was Mr. Babington.</p> <p>2 Q. Who is he?</p> <p>3 A. He's a lawyer.</p> <p>4 Q. Has he been your contact throughout</p> <p>5 this litigation, your direct contact?</p> <p>6 A. Initially, yes.</p> <p>7 Q. And then what happened?</p> <p>8 A. Then I became connected to Mr. Parker,</p> <p>9 and that's who my contact has been.</p> <p>10 Q. How is it that Mr. -- rephrase.</p> <p>11 Had you ever worked with Mr. Babington</p> <p>12 in the past before this litigation?</p> <p>13 A. No, I have not.</p> <p>14 Q. Was he the person who initially</p> <p>15 approached you?</p> <p>16 A. I believe so.</p> <p>17 Q. Why did he approach you? Do you have</p> <p>18 an understanding of why he contacted you?</p> <p>19 A. Other than my expertise, no.</p> <p>20 Q. Did he tell you that somebody had</p> <p>21 recommended that he speak to you?</p> <p>22 A. Not that I recall.</p> <p>23 Q. Do you hold yourself out through any</p> <p>24 service or network whereby people can find</p>	<p style="text-align: right;">Page 20</p> <p>1 Turner P. versus GWU, but I'm not certain that</p> <p>2 that's what that was, so I have to -- I stand</p> <p>3 corrected. I don't believe I gave a deposition</p> <p>4 for that then.</p> <p>5 BY MR. SLATER:</p> <p>6 Q. Well, could it be that you gave that</p> <p>7 deposition and didn't list it in your list of</p> <p>8 previous testimony?</p> <p>9 A. No, I think all my recent depositions</p> <p>10 are there. Anything is possible.</p> <p>11 Q. Could that deposition have been before</p> <p>12 January 1, 2012?</p> <p>13 A. I don't think so. It's certainly</p> <p>14 possible that it happened and it's not</p> <p>15 documented there. I don't keep a rigorous list</p> <p>16 of what depositions or testimonies I've given.</p> <p>17 But I went through, and I think it's likely to</p> <p>18 be completely accurate.</p> <p>19 Q. Who was the lawyer who you were</p> <p>20 working with in the Accutane litigation?</p> <p>21 A. His name is Matt Griffin.</p> <p>22 Q. What law firm?</p> <p>23 A. I don't know.</p> <p>24 Q. Do you know who took your deposition?</p>
<p style="text-align: right;">Page 19</p> <p>1 experts?</p> <p>2 A. No.</p> <p>3 Q. Have you ever been an expert for a</p> <p>4 pharmaceutical company in the past, besides this</p> <p>5 litigation?</p> <p>6 A. Once.</p> <p>7 Q. What did that involve?</p> <p>8 A. That was for Hoffmann-La Roche.</p> <p>9 Q. What drug?</p> <p>10 A. Accutane.</p> <p>11 Q. Did you testify?</p> <p>12 A. I did not testify.</p> <p>13 Q. What did you do in connection with the</p> <p>14 Accutane litigation?</p> <p>15 A. I reviewed some of the pathology</p> <p>16 cases, and I gave one deposition, which is</p> <p>17 documented in the report you received.</p> <p>18 Q. Which case is it that's listed in the</p> <p>19 report, just so that we have that in the record.</p> <p>20 (Whereupon, Turner Exhibit Number 4,</p> <p>21 Dr. Turner's General Causation</p> <p>22 Statement, was marked for</p> <p>23 identification.)</p> <p>24 A. I stand corrected. I was thinking of</p>	<p style="text-align: right;">Page 21</p> <p>1 A. No.</p> <p>2 Q. Other than the Accutane litigation,</p> <p>3 have you worked on behalf of any other</p> <p>4 pharmaceutical company?</p> <p>5 A. No, I have not.</p> <p>6 Q. Have you ever consulted for a</p> <p>7 pharmaceutical company outside of litigation?</p> <p>8 A. No.</p> <p>9 Q. Have you ever conducted a study with</p> <p>10 regard to a pharmaceutical drug?</p> <p>11 A. I did a small project looking at some</p> <p>12 binding interactions of an agent. It was a</p> <p>13 number of years ago. It was a small, several</p> <p>14 week project.</p> <p>15 Q. What was the agent?</p> <p>16 A. I don't remember. That's what I'm</p> <p>17 trying to think. I don't remember. I don't --</p> <p>18 I can remember the people in my research lab who</p> <p>19 did it, it was a small sponsored research</p> <p>20 agreement with that company. And other than</p> <p>21 that, I don't remember details.</p> <p>22 Q. Was anything published out of that</p> <p>23 small study?</p> <p>24 A. No.</p>

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<p>1 Q. Was anything presented or placed into</p> <p>2 an abstract or a poster presentation?</p> <p>3 A. No.</p> <p>4 Q. Were the results of that study ever</p> <p>5 shared publicly, or were they only shared with</p> <p>6 the company that funded it?</p> <p>7 A. I'm sure they weren't shared publicly.</p> <p>8 Q. Was that study meant to evaluate</p> <p>9 potential side effects or risks of this</p> <p>10 medication?</p> <p>11 A. No. It was a completely in vitro</p> <p>12 study.</p> <p>13 Q. Does that study have any relevance to</p> <p>14 the issues that you're going to -- that you've</p> <p>15 provided opinions on in this litigation?</p> <p>16 A. No, it does not.</p> <p>17 Q. Have you conducted any study of</p> <p>18 olmesartan?</p> <p>19 A. In the research lab?</p> <p>20 Q. Yes.</p> <p>21 A. In the research lab, I have not.</p> <p>22 Q. Did you suggest to anybody that you</p> <p>23 thought it would be prudent for you to perform</p> <p>24 any sort of in vitro study in a research lab</p>	<p>1 in olmesartan?</p> <p>2 A. Other than the medical literature that</p> <p>3 reported it.</p> <p>4 Q. Meaning you were familiar with the</p> <p>5 fact that some articles had been published in</p> <p>6 the literature, but other than that awareness</p> <p>7 you had no interest in olmesartan, correct?</p> <p>8 A. That's right.</p> <p>9 Q. You know Joseph Murray, correct?</p> <p>10 A. Yes, I do.</p> <p>11 Q. You respect him?</p> <p>12 A. Yes.</p> <p>13 Q. Is he considered perhaps one of the</p> <p>14 most -- rephrase.</p> <p>15 Is he considered the or one of the</p> <p>16 most respected celiac specialists in the world?</p> <p>17 A. I think he's one of the most</p> <p>18 respected, absolutely.</p> <p>19 Q. Joseph Murray is the world's authority</p> <p>20 regarding celiac and other disease processes,</p> <p>21 correct?</p> <p>22 A. I think specifically regarding celiac</p> <p>23 disease, yes.</p> <p>24 Q. Have you ever spoken with Dr. Murray</p>
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<p>1 regarding olmesartan?</p> <p>2 A. No.</p> <p>3 Q. The first time that you spoke with</p> <p>4 Mr. Babington was March 31, 2016, according to</p> <p>5 Exhibit 6, correct?</p> <p>6 A. We may have had e-mails before that,</p> <p>7 but something along those lines, yes.</p> <p>8 Q. It says there was a document review.</p> <p>9 What documents did you review at that initial</p> <p>10 meeting, do you know?</p> <p>11 A. I think they sent me a few articles</p> <p>12 related to olmesartan.</p> <p>13 Q. Do you remember what articles they</p> <p>14 were?</p> <p>15 A. I couldn't tell you exactly. I would</p> <p>16 -- I'd be speculating. I could speculate.</p> <p>17 Q. Have you published any articles with</p> <p>18 regard to olmesartan?</p> <p>19 A. No, I have not.</p> <p>20 Q. Have you given any presentations</p> <p>21 regarding olmesartan?</p> <p>22 A. I have not.</p> <p>23 Q. Am I correct that before you were</p> <p>24 retained in this litigation, you had no interest</p>	<p>1 regarding olmesartan?</p> <p>2 A. I have not.</p> <p>3 Q. Have you ever attended a presentation</p> <p>4 regarding olmesartan?</p> <p>5 A. I have not.</p> <p>6 Q. Before you were contacted to act as an</p> <p>7 expert in this litigation, what, if any,</p> <p>8 articles regarding olmesartan were you familiar</p> <p>9 with specifically?</p> <p>10 A. You know, I've been looking at a lot</p> <p>11 of articles in the months since then, and I</p> <p>12 don't think I could give you a clear list of</p> <p>13 what I had seen before and what I hadn't. I'm</p> <p>14 sure I'd seen the 2012 Mayo Clinic report. And</p> <p>15 I'm sure I'd seen some other papers, but I</p> <p>16 couldn't specifically tell you which ones.</p> <p>17 Q. The second invoice of May 24 bills for</p> <p>18 document preparation, protocol, phone call</p> <p>19 preparation, and phone call with Mr. Babington</p> <p>20 on May 14.</p> <p>21 Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. It says you spent two and a half hours</p> <p>24 on that day?</p>

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<p>1 A. No. The phone call was on May 14. I</p> <p>2 think the two and a half hours total was between</p> <p>3 April 23rd and May 24th.</p> <p>4 Q. Okay. Let me ask you again.</p> <p>5 The two and a half hours that you</p> <p>6 billed would have encompassed all of those</p> <p>7 activities you described between April 23 and</p> <p>8 the date of this invoice, May 24?</p> <p>9 A. Yes.</p> <p>10 Q. What protocol are you referring to?</p> <p>11 A. Mr. Babington asked me to put together</p> <p>12 a rough protocol of, if we were going to</p> <p>13 approach these biopsies in a standardized way,</p> <p>14 how we might go about doing that.</p> <p>15 Q. These were biopsies of patients who</p> <p>16 were having their cases reviewed as part of the</p> <p>17 litigation?</p> <p>18 A. Yes.</p> <p>19 Q. In your clinical practice, it's my</p> <p>20 understanding that you spend most of your time</p> <p>21 on research related activities, is that correct?</p> <p>22 A. Yes, about 70 percent.</p> <p>23 Q. You're at Brigham & Women's now. When</p> <p>24 did you return to Brigham & Women's?</p>	<p>1 Women's, how many biopsies have you looked at</p> <p>2 where there was a suspected or identified case</p> <p>3 of olmesartan enteropathy?</p> <p>4 A. None.</p> <p>5 Q. Have you ever looked at a biopsy for a</p> <p>6 patient where olmesartan enteropathy was part of</p> <p>7 the differential diagnosis?</p> <p>8 A. Yes.</p> <p>9 Q. In your clinical practice?</p> <p>10 A. No.</p> <p>11 Q. Is the first time that you ever looked</p> <p>12 at a biopsy for a patient where olmesartan</p> <p>13 enteropathy was a part of the differential</p> <p>14 diagnosis in connection with this litigation?</p> <p>15 A. Yes.</p> <p>16 Q. In connection with your work in this</p> <p>17 case, did you speak with any other physician or</p> <p>18 physicians regarding olmesartan enteropathy?</p> <p>19 A. I did not.</p> <p>20 Q. Not up to the present, you've never</p> <p>21 spoken to another doctor about the subject?</p> <p>22 A. I have not.</p> <p>23 Q. In order to prepare the protocol, what</p> <p>24 did you consult in order to prepare the protocol</p>
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<p>1 A. Last February.</p> <p>2 Q. At Brigham & Women's, do you have any</p> <p>3 clinical responsibilities?</p> <p>4 A. Yes.</p> <p>5 Q. What are your clinical</p> <p>6 responsibilities at the Brigham?</p> <p>7 A. It's exclusively GI pathology, almost</p> <p>8 exclusively biopsies.</p> <p>9 Q. How many hours a week do you have</p> <p>10 clinical responsibility at Brigham & Women's?</p> <p>11 A. I have eight weeks per year, so you</p> <p>12 can break that out any way you like.</p> <p>13 Q. Since you went to Brigham & Women's,</p> <p>14 how many times have you looked at biopsies in</p> <p>15 connection with suspected or identified celiac</p> <p>16 disease?</p> <p>17 A. I couldn't give you an exact number,</p> <p>18 but I'm sure it's quite a few. We see a lot of</p> <p>19 those.</p> <p>20 Q. Estimate for me, how many have you</p> <p>21 seen?</p> <p>22 A. Well, an estimate, maybe a couple</p> <p>23 hundred.</p> <p>24 Q. In the time you've been at Brigham &</p>	<p>1 to look at olmesartan enteropathy biopsies?</p> <p>2 A. I essentially put together a protocol</p> <p>3 for how I would morphometrically assess a small</p> <p>4 intestinal biopsy.</p> <p>5 Q. The third of the invoices within</p> <p>6 Exhibit 6 is dated October 9, 2016, and there's</p> <p>7 a description. Does that describe the work that</p> <p>8 you did between May 24 and October 9?</p> <p>9 A. Yes, it does.</p> <p>10 Q. In your career, outside of this</p> <p>11 litigation, have you ever been asked to consult</p> <p>12 on the question of whether or not a patient had</p> <p>13 olmesartan related illness?</p> <p>14 A. I have not.</p> <p>15 Q. Do you know anybody that you've worked</p> <p>16 with who has ever -- rephrase.</p> <p>17 Are there any other pathologists</p> <p>18 you've worked with, either at Brigham & Women's</p> <p>19 or at your prior institutions where you were</p> <p>20 employed, where anybody you worked with was</p> <p>21 evaluating, to your knowledge, whether a patient</p> <p>22 had an olmesartan related illness?</p> <p>23 A. Not to my knowledge.</p> <p>24 Q. Let's look back at the deposition</p>

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<p>1 notice -- your response actually, Exhibit 2. 2 Number 3 is "Copies of any notes or 3 other documentation, including PowerPoints, for 4 any presentations given by Dr. Turner with 5 regard to (1) Olmesartan/Benicar, and (2) celiac 6 disease." 7 Do you see that request? 8 A. Yes, I do. 9 Q. Have you ever given any such 10 presentation, meaning a presentation with regard 11 to olmesartan or Benicar? Let's start there. 12 A. No. 13 Q. Have you ever given a presentation 14 with regard to celiac disease? 15 A. In the past I've done a lot of 16 teaching in the medical school. Now I write 17 textbook chapters that are used worldwide, and 18 in those, celiac disease is certainly discussed. 19 Q. Let's talk about a presentation to 20 other physicians at a professional conference or 21 a professional organization. Have you ever 22 given a presentation on celiac disease in that 23 context? 24 A. It's possible. I can't be specific.</p>	<p>1 celiac. You would not be one of those, correct? 2 A. I guess I don't agree with your 3 question. 4 Q. Are there GI pathologists who have 5 published on celiac? 6 A. Sure. 7 Q. Are there GI pathologists that one 8 would think of if they had a complex case they 9 were looking at and wanted the input of somebody 10 who had a lot of experience and knowledge 11 regarding celiac who people would think to 12 consult around the country -- 13 A. No, I don't think so. 14 Q. -- to help with the interpretation of 15 a biopsy slide? 16 A. No, I don't think so. Other than 17 generally skilled GI pathologists. 18 Q. Request number 4 is "Copies of any 19 documents or articles relied upon for the 20 opinions set forth in the report served, if not 21 listed in the report." And from reading your 22 response, my understanding is you're not 23 producing anything, because anything you relied 24 on is actually listed in the report and the</p>
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<p>1 Q. Nothing you can point to right now? 2 A. Nothing specific. I was chair of the 3 intestinal disorders section of the American 4 Gastroenterological Association, and celiac 5 disease is the primary disease of that section, 6 and so it's very possible in the course of those 7 duties I was involved in sessions related to 8 celiac disease. 9 I think I may have also done a session 10 related to celiac disease in some of our 11 professional education courses for pathologists 12 at University of Chicago, but honestly, it's 13 been a couple years, and I can't remember in 14 detail. 15 Q. You're not considered in the field 16 that you practice in to be an authority on 17 celiac disease, are you? 18 A. I'm considered to be an expert in GI 19 pathology generally. I don't know any GI 20 pathologists who are experts just in celiac 21 disease. 22 Q. I understand that there are some GI 23 pathologists who are known to have a special 24 interest or a subspecialization regarding</p>	<p>1 reliance list, is that correct? 2 A. Well, I also relied on my general 3 knowledge, so I think that we couldn't do that. 4 But specific articles with specific 5 facts that are related to this I think are 6 listed in my report and my general reliance 7 list. 8 Q. With regard to any particular document 9 that you're relying on, those are listed either 10 in the report or the reliance lists, correct? 11 A. Again, you know, I think there's a 12 broad fund of medical knowledge that I've 13 accumulated over years, sometimes from specific 14 articles, sometimes from textbooks, sometimes 15 from multiple experiences, I can't tell you that 16 none of those played into my thinking. But I 17 think the specific documents related to 18 olmesartan are, for the most part, included in 19 my reliance lists. 20 Q. You understand that the reason I'm 21 asking this is so that, if you testify, I will 22 know in advance which specific documents or 23 specific articles you might refer to or rely on 24 for your opinions. In that context, those</p>

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<p>1 documents or articles are listed in your report 2 or in the reliance lists, correct? 3 A. I don't anticipate calling up any 4 specific articles that aren't listed there, or 5 in my CV, I guess. 6 Q. Is there anything that you've asked 7 for from the lawyers who retained you or were 8 working with you that they did not provide you? 9 A. No. 10 Q. Are there any documents or materials 11 that you were shown with regard to olmesartan 12 that you did not list in the reliance list or 13 the report? 14 A. Yesterday -- Tuesday, Tuesday I 15 received an e-mail with some of the internal 16 documents from Daiichi, and I don't think I had 17 time to list those. I just looked at those 18 briefly. They've been mentioned in one of the 19 depositions I'd seen most recently from 20 Mr. Leffler, and -- from Dr. Leffler, and I 21 wanted to see for myself. So I looked at those 22 enough to confirm that they were what I 23 anticipated. 24 Q. Whatever documents you looked at this</p>	<p>1 me you saw yesterday, and it doesn't list 2 anything other than what's in the report, and I 3 had no notice before now. You realize that, 4 right? 5 A. I need to clarify. I told you I 6 hadn't seen the deposition notice until just 7 now. 8 Q. Oh, I thought you said you'd seen it. 9 A. Look back at your notes. 10 Q. The record will speak for itself. 11 A. Yeah. 12 Q. So is there anything that you saw this 13 week, these so-called internal documents, that 14 you are relying on for the opinions that you are 15 offering in this case? 16 A. Can you restate that? 17 Q. Sure. 18 Is there anything that you saw in 19 these internal documents that you saw this week 20 that you are relying on now for the opinions 21 you're offering in this case? 22 A. I think they would be supportive, and 23 I've now internalized them into my knowledge, so 24 I can't tell you that I wouldn't refer to one of</p>
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<p>1 week, or Tuesday I guess you said, did they have 2 any impact on your opinions? 3 A. I think they were consistent with what 4 I expected from MedWatch reports, and the 5 internal documentations. MedWatch reports are 6 fairly standard, and I know what they look like. 7 The internal documentation was an 8 analysis that was mostly encompassed by the 9 Mini-Sentinel reports that I'd seen, so I don't 10 think they ended up changing my opinion. I do 11 think they added to data supporting that. 12 Q. Do you have those documents with you 13 today? 14 A. I do. 15 Q. All right. Did you think maybe you 16 should let me know before we started the 17 deposition that you'd reviewed other documents 18 so I could actually have those and be prepared 19 for that? Did you think that would have been a 20 good thing to do? 21 A. I believed that Mr. Parker would do 22 that. 23 Q. Well, now I'm telling you, you see the 24 response to the deposition notice which you told</p>	<p>1 them. I'm sure you've seen them. 2 Q. Tell me what documents you have 3 internalized into your knowledge that you are 4 relying on for your opinions in this case? 5 A. You just asked two questions. Which 6 one? 7 Q. Well, here's the thing. If you read a 8 document, if you're not relying on it, then we 9 can say we can push those to the side. I only 10 care about documents you're actually relying on 11 for your opinions. So to be very clear, just 12 let me ask you the question clean. 13 The documents you saw this week, are 14 you relying on any particular document that was 15 a so-called internal document for the opinions 16 that you're offering in this litigation? 17 A. It depends on what you ask me. 18 Q. Well, you served a report, we marked 19 it as Exhibit 4, right? 20 A. Yes. 21 Q. That's the only report you've written 22 in this case, right? 23 A. No. 24 Q. Let me rephrase.</p>

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<p style="text-align: right;">Page 38</p> <p>1 With regard to the subject of general 2 causation, Exhibit 4 is the only report you have 3 written in this case, right? 4 A. Yes. 5 Q. Does that report contain each of your 6 opinions? 7 A. Yes, it does. 8 Q. In the course of the report, you 9 analyzed certain facts and certain articles. 10 Are those facts and articles that you discuss 11 those that you felt were most important to you 12 in forming your opinions that are set forth in 13 that report? 14 A. I think those were most important, 15 yes. 16 Q. Is there anything that you saw this 17 week, these so-called internal documents, which 18 you feel is so important that you would have 19 listed it in your report if you had seen it 20 before you wrote your report? 21 A. I think I would have cited it, the 22 MedWatch reports, as further anecdotal case 23 reports that were not particularly 24 well-controlled, like most of the case reports</p>	<p style="text-align: right;">Page 40</p> <p>1 MedWatch reports. 2 MR. PARKER: Well, I think -- well, 3 you'll ask the witness, but that's all he was 4 sent. 5 A. There was -- 6 BY MR. SLATER: 7 Q. Dr. Turner, you saw MedWatch reports, 8 you testified to that under oath, right? 9 A. Right. There was a table -- 10 Q. How many? 11 A. There was a table summarizing MedWatch 12 reports at the end of one of those. 13 Q. So you didn't see the actual MedWatch 14 reports, you just saw the table summarizing the 15 MedWatch reports? 16 A. In this case I don't think I saw the 17 actual full reports. I saw the summaries of the 18 reports. I have seen a couple MedWatch reports 19 in the course of my meetings with Mr. Parker and 20 Mr. Christian. 21 But I guess you're right that I saw 22 the summary of the reports individually, each 23 one had its own line and lots of details, but I 24 did see the actual MedWatch forms.</p>
<p style="text-align: right;">Page 39</p> <p>1 that I -- the published case reports that I 2 referred to, but I don't think they would have 3 changed anything substantive. 4 Q. Do you have a list of what you 5 reviewed? 6 A. I do. 7 Q. The internal documents you saw this 8 week which I never knew about until now? 9 A. Yes. I'm sure you've seen them. 10 Q. No, no. Do you have a list of what 11 you saw? 12 A. Yes, I think I do. 13 Q. All right. How am I going to get 14 that? How can I have that sent to me right now? 15 MR. SLATER: Mr. Parker, do you have 16 the ability to e-mail me the list? 17 MR. PARKER: It's two documents, Adam, 18 the Caspard report and the Parker report. 19 That's it. 20 MR. SLATER: I'm sorry, you said the 21 Caspard report and what? 22 MR. PARKER: And the Parker report. 23 That's it. Two documents. 24 MR. SLATER: Well, he just said he saw</p>	<p style="text-align: right;">Page 41</p> <p>1 Q. When did you see MedWatch forms during 2 the course of your meetings? When did you see 3 those? 4 A. In the last week, I believe 5 Mr. Christian showed me a couple of them. 6 Q. Which ones? 7 A. I don't remember. 8 Q. Do you have them there? 9 A. No. 10 Q. How many did you see? 11 A. Less than five, a handful. They were 12 consistent with those in the tables of the 13 documents. That was part of why I was asked for 14 those documents. 15 MR. SLATER: Move to strike "they were 16 consistent," etcetera. 17 Q. Other than the less than five MedWatch 18 reports that you saw in the last week, and the 19 Caspard report and the Parker reports which you 20 were shown two days ago, have you seen any other 21 internal documents from Daiichi? 22 A. I don't believe so. 23 Q. Do you have any knowledge of whether 24 or not the Caspard report -- which addressed</p>

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<p>1 celiac disease, correct?</p> <p>2 A. I believe that's true.</p> <p>3 Q. Do you have any knowledge as to</p> <p>4 whether that includes all MedWatch reports that</p> <p>5 should have been included in that report if the</p> <p>6 inclusion criteria were followed strictly within</p> <p>7 Daiichi?</p> <p>8 THE VIDEOGRAPHER: Mr. Slater, you</p> <p>9 broke up on that question. Could you repeat the</p> <p>10 question?</p> <p>11 MR. SLATER: Sure. I'll ask it again.</p> <p>12 Q. Do you have any knowledge as to</p> <p>13 whether or not the Caspard report actually</p> <p>14 includes all of the celiac reports that should</p> <p>15 be included in that report?</p> <p>16 A. I didn't do my own search of MedWatch</p> <p>17 reports, so I couldn't comment on that.</p> <p>18 Q. You never read Mr. Caspard's</p> <p>19 deposition, right?</p> <p>20 A. I did not read Mr. Caspard's</p> <p>21 deposition.</p> <p>22 Q. Have you seen any deposition of any</p> <p>23 company witness from Daiichi?</p> <p>24 A. No.</p>	<p>1 become an issue, but I'm going to potentially</p> <p>2 request additional time beyond the seven hours,</p> <p>3 because I'm spending all this time going through</p> <p>4 documents that I had no idea he had seen until</p> <p>5 the middle of the deposition. It probably won't</p> <p>6 be an issue, but if it becomes an issue I just</p> <p>7 want to state it for the record.</p> <p>8 MR. PARKER: You did that.</p> <p>9 A. I don't think I -- I expect I should,</p> <p>10 but I'm not seeing a hard copy of the other</p> <p>11 report. It may be stapled together with</p> <p>12 something else.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. We marked the Parker report, right?</p> <p>15 A. Yes.</p> <p>16 Q. Do you see the conclusion by</p> <p>17 Dr. Crawford Parker where he says there's no</p> <p>18 need to add a warning to the label about</p> <p>19 sprue-like enteropathy, or words to that effect?</p> <p>20 A. Can you tell me where you're referring</p> <p>21 to?</p> <p>22 Q. I don't have the report in front of</p> <p>23 me, I didn't know you'd seen it, so I'm going by</p> <p>24 memory. My understanding is that was his</p>
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<p>1 Q. Other than the Caspard report, the</p> <p>2 Parker report, and the less than five MedWatch</p> <p>3 reports, just to be very clear, you have not</p> <p>4 seen any other Daiichi document, correct?</p> <p>5 A. Correct.</p> <p>6 Q. The Parker report, is that the one</p> <p>7 that concluded there was no need to add a</p> <p>8 warning to the label about sprue-like</p> <p>9 enteropathy?</p> <p>10 A. I need to look back at it.</p> <p>11 Q. Let's throw a sticker on that.</p> <p>12 A. The Parker report? Did you just ask</p> <p>13 about the Parker report?</p> <p>14 Q. The Parker report. Let's mark it just</p> <p>15 so we know what you're looking at.</p> <p>16 (Whereupon, Turner Exhibit Number 7,</p> <p>17 Parker report titled Olmesartan and</p> <p>18 Sprue-like Enteropathy, Bates</p> <p>19 OLM-DSI-0003347042 through 3347100,</p> <p>20 was marked for identification.)</p> <p>21 MR. SLATER: Let's mark that 7. And</p> <p>22 let's mark, if you have the Caspard report</p> <p>23 handy, let's mark that 8.</p> <p>24 Bruce, I don't know if it's going to</p>	<p>1 conclusion.</p> <p>2 (Witness reviewing document.)</p> <p>3 A. He says that "Based on this</p> <p>4 assessment, no change to the existing olmesartan</p> <p>5 product labeling is recommended." And then he</p> <p>6 says --</p> <p>7 BY MR. SLATER:</p> <p>8 Q. Are you aware that --</p> <p>9 A. Can you finish my answer?</p> <p>10 Q. I'm sorry, I didn't realize. I</p> <p>11 thought you were done. I apologize.</p> <p>12 A. No. That's becoming common.</p> <p>13 "In view of the findings and</p> <p>14 conclusions of this and prior assessments,</p> <p>15 Daiichi-Sankyo proposes to continue" --</p> <p>16 MR. PARKER: Slow down. We have to</p> <p>17 take this down, please.</p> <p>18 A. Sorry, sorry.</p> <p>19 He goes on to say that "Daiichi-Sankyo</p> <p>20 proposes to continue routine safety surveillance</p> <p>21 for sprue-like enteropathy and celiac disease."</p> <p>22 So I think what he's saying is there's not</p> <p>23 enough -- my synthesis is that there's not</p> <p>24 enough data to do a lot right now, but that this</p>

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<p style="text-align: right;">Page 46</p> <p>1 should be watched.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. Do you know the date of that report?</p> <p>4 A. It's dated September 28th, 2012. They</p> <p>5 were obviously aware -- although that's before</p> <p>6 the publication date, they were obviously aware</p> <p>7 of the Mayo report at that time. I guess it's</p> <p>8 just after the publication date of the Mayo</p> <p>9 report. Excuse me.</p> <p>10 Q. Are you aware that the position</p> <p>11 Mr. Parker took in that report was rejected by</p> <p>12 the FDA -- rephrase.</p> <p>13 Are you aware that the FDA reached a</p> <p>14 different conclusion and required that a warning</p> <p>15 be added to the label for olmesartan?</p> <p>16 A. I'm aware that the FDA changed the</p> <p>17 label, or recommended the changes to the label.</p> <p>18 Q. What, if anything, is significant to</p> <p>19 you about the Parker report?</p> <p>20 A. What was helpful to me about the</p> <p>21 Parker report was the specifics of individual</p> <p>22 cases. And appended to it is a detailed table</p> <p>23 that lists individual cases in the MedWatch</p> <p>24 report, and I think it's a fairly exhaustive</p>	<p style="text-align: right;">Page 48</p> <p>1 which did have the clinical picture of</p> <p>2 olmesartan enteropathy that aren't listed? Do</p> <p>3 you know whether there are any such reports?</p> <p>4 A. So you've made a conclusion in your</p> <p>5 question that I can't agree with.</p> <p>6 Q. Do you know whether there are other</p> <p>7 reports that aren't listed in that report where</p> <p>8 patients either had diarrhea and weight loss or</p> <p>9 serious diarrhea that aren't included?</p> <p>10 A. I don't know that.</p> <p>11 Q. Do you know who Crawford Parker is?</p> <p>12 A. No, I don't, other than his title</p> <p>13 here.</p> <p>14 Q. With regard to the Caspard report,</p> <p>15 what, if anything, about it is significant to</p> <p>16 you?</p> <p>17 A. You know, I can't remember anything</p> <p>18 specific. I'm sorry that I don't have a copy of</p> <p>19 it with me.</p> <p>20 Q. With regard to the less than five</p> <p>21 MedWatch reports that you reviewed a week or so</p> <p>22 ago, or in the last week, what, if anything, can</p> <p>23 you specifically point to in your deposition</p> <p>24 right now that you would say is significant to</p>
<p style="text-align: right;">Page 47</p> <p>1 list. I can't promise that everything is there,</p> <p>2 but it's a fairly exhaustive list.</p> <p>3 Q. You think -- rephrase.</p> <p>4 You're trusting that Crawford Parker</p> <p>5 included all the adverse event reports that</p> <p>6 would have potentially implicated sprue-like</p> <p>7 enteropathy? Was that your understanding?</p> <p>8 A. No, I think I just said the exact</p> <p>9 opposite.</p> <p>10 Q. You did? Tell me, what was your</p> <p>11 understanding as to what the inclusion criteria</p> <p>12 was for this report.</p> <p>13 A. That's a different question than you</p> <p>14 asked a moment ago. Let me find those to be</p> <p>15 sure that I'm not remembering incorrectly.</p> <p>16 (Witness reviewing document.)</p> <p>17 A. So they used several approaches. The</p> <p>18 first was patients with diarrhea and weight</p> <p>19 loss. The second was serious diarrhea. That</p> <p>20 was it.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. Do you know whether Daiichi had in its</p> <p>23 database additional adverse event reports, not</p> <p>24 including the Parker report, which would have --</p>	<p style="text-align: right;">Page 49</p> <p>1 you about those MedWatch reports, specific to</p> <p>2 each one?</p> <p>3 A. I think that what's specific to the</p> <p>4 MedWatch reports is the same thing that I found</p> <p>5 in each of the case reports, is that they were</p> <p>6 wholly uncontrolled, and showed correlation, but</p> <p>7 no data really supporting causation.</p> <p>8 Q. What does correlation mean?</p> <p>9 A. Correlation means if something, A,</p> <p>10 happened, then more often than not B will follow</p> <p>11 or be accompanying that.</p> <p>12 Q. The MedWatch reports you saw you</p> <p>13 believe did show a correlation between</p> <p>14 olmesartan and gastrointestinal illness,</p> <p>15 correct?</p> <p>16 A. In some individual cases there was a</p> <p>17 correlation.</p> <p>18 Q. Were you shown any adverse event</p> <p>19 reports in which Daiichi performed a causality</p> <p>20 assessment internally, when their physicians</p> <p>21 actually evaluated causality?</p> <p>22 A. I don't think so.</p> <p>23 Q. Do you know whether Daiichi actually,</p> <p>24 their internal physicians actually evaluated any</p>

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<p style="text-align: right;">Page 50</p> <p>1 adverse event reports and made the finding that</p> <p>2 the gastrointestinal conditions related in the</p> <p>3 MedWatch report was definitely related to the</p> <p>4 use of olmesartan? Do you know if that was</p> <p>5 concluded in any MedWatches?</p> <p>6 A. I'm not aware of any of those.</p> <p>7 Q. If those existed, that would be</p> <p>8 something that would be relevant to you in</p> <p>9 reviewing MedWatch reports, right? If they're</p> <p>10 going to show you some, they should show you</p> <p>11 those, right?</p> <p>12 A. I would think those would be worth</p> <p>13 seeing.</p> <p>14 Q. Okay. Did you ask, when you were</p> <p>15 provided less than five MedWatch reports, if</p> <p>16 there were any others that might be of</p> <p>17 significance?</p> <p>18 A. I did.</p> <p>19 Q. And what were you told?</p> <p>20 A. I was told that the stack pretty much</p> <p>21 looked like this. It was in reference to the</p> <p>22 stack that Dr. Leffler went through where he</p> <p>23 threw out a couple of them, but felt that the</p> <p>24 others were valid, and so I asked to see those,</p>	<p style="text-align: right;">Page 52</p> <p>1 the response, request number 5, "Any</p> <p>2 illustrations, PowerPoints, images, charts,</p> <p>3 tables or demonstrative exhibits that may be</p> <p>4 used in connection with the Daubert hearing or</p> <p>5 testimony of Dr. Turner."</p> <p>6 Do you see where I just read?</p> <p>7 A. Can you repeat that? You broke up.</p> <p>8 Q. Do you see number 5?</p> <p>9 A. Yes, I do.</p> <p>10 Q. Have you prepared any illustrations or</p> <p>11 PowerPoints regarding your opinions in this</p> <p>12 litigation?</p> <p>13 A. I have not.</p> <p>14 Q. Have you prepared -- well, rephrase.</p> <p>15 Are there any images, charts, or</p> <p>16 tables that, if you were testifying, that you</p> <p>17 would consider using as part of your testimony?</p> <p>18 A. I've taken photomicrographs of some of</p> <p>19 the cases, so in specific cases.</p> <p>20 Q. You're talking about cases you've</p> <p>21 reviewed?</p> <p>22 A. Yes.</p> <p>23 Q. Anything else?</p> <p>24 A. Not related to general causation, no.</p>
<p style="text-align: right;">Page 51</p> <p>1 and I was shown some that I was told were</p> <p>2 representative of the whole. I clearly didn't</p> <p>3 have the time at that late date to go through</p> <p>4 all 62.</p> <p>5 Q. Are you aware of whether the highest</p> <p>6 level executive in the pharmacovigilance</p> <p>7 department testified as to his opinion as to</p> <p>8 whether any MedWatch reports, the adverse events</p> <p>9 reflected in MedWatch reports, were -- there was</p> <p>10 a causal relationship between olmesartan and the</p> <p>11 gastrointestinal disorder reflected? Do you</p> <p>12 know about that?</p> <p>13 MR. PARKER: Objection.</p> <p>14 A. I'm not aware of any depositions.</p> <p>15 BY MR. SLATER:</p> <p>16 Q. You're not able to tell me, as you sit</p> <p>17 here now, which MedWatch reports you actually</p> <p>18 saw, right? You can't identify those for me,</p> <p>19 right?</p> <p>20 A. No. As you know, they're only</p> <p>21 identified by a series of numbers, and I didn't</p> <p>22 write down the numbers, and I certainly don't</p> <p>23 remember them.</p> <p>24 Q. Let's look at the deposition notice,</p>	<p style="text-align: right;">Page 53</p> <p>1 Q. Request 6 is "Documentation of any</p> <p>2 research grant you have been provided to study</p> <p>3 Olmesartan/Benicar, or celiac disease, or health</p> <p>4 effects potentially related thereto."</p> <p>5 Are there any such research grants?</p> <p>6 A. No.</p> <p>7 Q. Look at request number 7, please.</p> <p>8 "Copies of any documents including protocols or</p> <p>9 information about medication side effects, from</p> <p>10 any hospital or academic institution where you</p> <p>11 have worked, had an appointment, or had</p> <p>12 privileges, which set forth information related</p> <p>13 to the diagnosis or treatment of any</p> <p>14 Olmesartan/Benicar related medical conditions or</p> <p>15 side effects."</p> <p>16 A. I'm not aware of any.</p> <p>17 Q. Are there any such documents that</p> <p>18 you're aware of?</p> <p>19 A. I'm not aware of any.</p> <p>20 Q. Now let's look at your report,</p> <p>21 Exhibit 4.</p> <p>22 A. Yes.</p> <p>23 Q. Exhibit 4 is several documents that we</p> <p>24 were provided together as one group, and at the</p>

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<p style="text-align: right;">Page 54</p> <p>1 beginning is your report on general causation in 2 this litigation, correct? 3 A. Correct. 4 Q. After that, starting on Page 10, is a 5 list of literature cited, and that literature, 6 that was actually cited in the report? 7 A. Correct. 8 Q. On Page 16 is previous testimony. And 9 are those the only times that you've testified, 10 or the only cases you've testified in since 11 January 1, 2012 -- 12 A. To the best of my knowledge -- 13 Q. -- other than perhaps that Accutane 14 case we talked about? 15 A. To the best of my knowledge, this is 16 complete. 17 Q. After that page is a document starting 18 with Page 1. Is that your up-to-date curriculum 19 vitae as of January 31, 2017? 20 A. Yes, it is. 21 Q. Let's look at Exhibit 5. 22 (Whereupon, Turner Exhibit Number 5, 23 Document titled Supplemental Reliance 24 List, was marked for identification.)</p>	<p style="text-align: right;">Page 56</p> <p>1 There's one, I'm sorry, there's one that I could 2 not get the full text of, so I haven't read that 3 entire article. 4 Q. Which one is that? 5 A. I believe it was Laeis, L-A-E-I-S, is 6 the first author's name. As far as I could 7 tell, that's not available electronically. I 8 did put in a request for it, but I was unable to 9 get it. 10 Q. In your review of medical literature, 11 can you point to any article in the 12 peer-reviewed literature where the authors 13 reached the conclusion explicitly that 14 olmesartan is not associated with sprue-like 15 enteropathy? 16 A. Can you state that more specifically? 17 Q. Well, let's use the term 18 olmesartan-associated enteropathy. You 19 understand what that term means? 20 A. I understand that people have used 21 that term. I'm not sure I entirely understand 22 or agree with how people have used it. 23 Q. You've used that term, right? 24 A. I have not.</p>
<p style="text-align: right;">Page 55</p> <p>1 BY MR. SLATER: 2 Q. Titled "Supplemental Reliance List." 3 What is that document? 4 A. It seems to be -- I see. It's stuck 5 together. Yes, I have it. 6 Q. What is that document? 7 A. I went through -- in response to your 8 request, I went through my library of articles 9 and pulled those that I thought I had relied on 10 in preparing the report for information, but may 11 or may not have specifically cited in the 12 report. 13 Q. Did you compile this reliance list 14 that's Exhibit 5, or did someone else do it for 15 you? 16 A. No, I compiled it. 17 Q. You typed all those articles yourself? 18 THE VIDEOGRAPHER: You broke up, sir. 19 Q. You typed this up yourself? 20 A. I copied and pasted them from my 21 EndNote library. 22 Q. Is it your testimony that you've read 23 each article on the supplemental reliance list? 24 A. I've read them, maybe not recently.</p>	<p style="text-align: right;">Page 57</p> <p>1 Q. You don't know what 2 olmesartan-associated enteropathy means? 3 A. I've used that term to reflect what 4 others have written in their texts, but I have 5 not used it myself because I don't think it 6 represents something that's factually based. 7 Q. What is your understand -- well, let 8 me ask you this. 9 Is there any article in the 10 peer-reviewed literature that reaches the 11 conclusion that olmesartan does not cause in any 12 patients what has been termed in the medical 13 literature olmesartan-associated enteropathy or 14 sprue-like enteropathy? 15 A. Not that I'm aware. 16 Q. Same question with regard to 17 association, is there any article that concludes 18 that there is not an association between the 19 two? 20 A. Are we talking about in any patient, 21 or in epidemiological studies, or groups of 22 patients? You need to be more specific in your 23 question. 24 Q. Is there any article in the published</p>

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<p style="text-align: right;">Page 58</p> <p>1 peer-reviewed medical literature you can point 2 to that concludes explicitly that there is no 3 association between olmesartan and what has been 4 termed in the literature olmesartan-associated 5 enteropathy or sprue-like enteropathy? Any 6 article that reaches that conclusion? 7 A. Yes, there's several. 8 Q. That says there's no association? 9 A. That says there was no association 10 detected in their study. 11 Q. Which articles say there's no 12 association. Well, let me stop you for a 13 second, stop you for a second. 14 My question is not somebody saying 15 whether or not they found an association in 16 their study. My question is, is there any 17 article in the peer-reviewed literature where 18 there is an explicit conclusion that olmesartan 19 is not associated with olmesartan-associated 20 enteropathy as that term is used in the 21 literature, or sprue-like enteropathy, any 22 article that reaches that explicit conclusion? 23 A. Well, I think failure to detect an 24 association in a highly powered study would come</p>	<p style="text-align: right;">Page 60</p> <p>1 A. I'm not sure I do, because if you're 2 asking what I think you're asking, there could 3 be a thousand studies that say we didn't find an 4 association and one study that says we found an 5 association, and I would be -- it would be the 6 appropriate answer to say no, there's no 7 articles that concluded there was absolutely no 8 association in any way possible ever? Is that 9 what you're asking? 10 Q. That's what I'm asking. 11 A. Yeah, there's no articles that 12 conclude absolutely positively there could 13 never, ever be an association between olmesartan 14 and enteropathy. 15 Q. You're familiar with the Rubio-Tapia 16 article, correct? 17 A. Which one? 18 Q. 2012, the first major article in this 19 area. 20 A. Yes. 21 Q. The authors in that study include 22 Joseph Murray, correct? 23 A. Yes. 24 Q. Dr. Murray and his co-authors conclude</p>
<p style="text-align: right;">Page 59</p> <p>1 to that conclusion to the extent that it's 2 possible to prove a negative. Proving a 3 negative is obviously impossible or very 4 difficult. So it depends how you interpret 5 that. 6 MR. SLATER: Move to strike. 7 Q. Is there any article that reaches that 8 conclusion that I just asked you, explicitly 9 states there is no association? 10 A. Yes. 11 Q. Are you saying that there's articles 12 where a study was done and they did not find an 13 association in their study? Because that's not 14 what I'm asking you. 15 MR. PARKER: Objection. 16 BY MR. SLATER: 17 Q. That's a different conclusion than 18 what I'm asking you about. 19 MR. PARKER: Objection. 20 Argumentative. 21 You may answer. 22 A. I'm saying -- 23 BY MR. SLATER: 24 Q. Do you understand my question?</p>	<p style="text-align: right;">Page 61</p> <p>1 that there is an association between olmesartan 2 and either olmesartan-associated enteropathy or 3 sprue-like enteropathy, whatever you want to 4 call it, they concluded there was an 5 association, correct? 6 A. Let me pull the article, please. 7 (Witness reviewing document.) 8 A. What they say at the end of the 9 article is suggesting that perhaps, and I'm 10 going to paraphrase a little bit, this may be 11 another example of drug-associated enteropathy 12 of which the medical community should be aware. 13 Elsewhere in the article they conclude 14 that further study is needed. I'm looking for 15 the exact phraseology. I don't think they 16 conclude that there's a causative relationship, 17 I think they're actually very careful not to 18 conclude that. And I'm looking to see if the 19 exact words you said, an association, are 20 listed. 21 BY MR. SLATER: 22 Q. Check the title. 23 A. That's a little bit different than 24 what you said.</p>

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<p>1 Q. What's the title of the article?</p> <p>2 A. The title says "Severe Spruelike</p> <p>3 Enteropathy Associated With Olmesartan."</p> <p>4 Q. You understand what those words mean,</p> <p>5 right?</p> <p>6 A. Of course I do.</p> <p>7 Q. So the title of the article is stating</p> <p>8 that severe sprue-like enteropathy is associated</p> <p>9 with olmesartan, that's the actual title of the</p> <p>10 article, right?</p> <p>11 A. That is the title.</p> <p>12 Q. Did you see in the article where they</p> <p>13 said they did not believe this was a chance</p> <p>14 association?</p> <p>15 A. I did. I also saw they said that it's</p> <p>16 a case series that lacks all information</p> <p>17 necessary to prove causality, but rather</p> <p>18 reflects an association.</p> <p>19 MR. SLATER: Move to strike after "I</p> <p>20 did."</p> <p>21 Q. So you agree with me that the authors</p> <p>22 of the Rubio-Tapia 2012 article titled "Severe</p> <p>23 Spruelike Enteropathy Associated With</p> <p>24 Olmesartan" stated explicitly that they did not</p>	<p>1 Looking in the second paragraph of the</p> <p>2 discussion on Page 735, let's go to the last</p> <p>3 sentence of that paragraph that starts</p> <p>4 "Resolution."</p> <p>5 Do you see the word "resolution"?</p> <p>6 A. Yes, I do.</p> <p>7 Q. It says, "Resolution of the presenting</p> <p>8 symptoms and subsequent histologic improvement</p> <p>9 after suspension of olmesartan, in the absence</p> <p>10 of clinical evidence of other diseases</p> <p>11 associated with enteropathy, suggest that the</p> <p>12 association is not likely to be due to chance."</p> <p>13 Do you see that?</p> <p>14 A. Yes, I see that.</p> <p>15 Q. There is a spectrum of association,</p> <p>16 correct? There's chance associations, and then</p> <p>17 there's causal associations at the other end of</p> <p>18 the spectrum, correct?</p> <p>19 A. Correct.</p> <p>20 Q. So the authors concluded this is not a</p> <p>21 chance association?</p> <p>22 MR. PARKER: Objection.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. They're saying that it's at the other</p>
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<p>1 believe this was a chance association? You</p> <p>2 agree with that statement, correct?</p> <p>3 A. I'm looking, because I don't think</p> <p>4 that's their exact words. I do see, again,</p> <p>5 where they say that this case series lacks</p> <p>6 information necessary to prove causality, and</p> <p>7 I'm looking for -- I do remember something to</p> <p>8 the effect of that they thought it was not</p> <p>9 likely due to chance, but they didn't say that</p> <p>10 it's not due to chance. I'm looking for the</p> <p>11 wording.</p> <p>12 MR. SLATER: I'm going to move to</p> <p>13 strike.</p> <p>14 Q. Look at Page 735, please, the</p> <p>15 "Discussion" section. The second paragraph</p> <p>16 under the Discussion section starts "We</p> <p>17 acknowledge."</p> <p>18 Do you see where I am?</p> <p>19 A. Yes, that's what I was reading from.</p> <p>20 Q. In the first sentence they state that</p> <p>21 this reflects an association, right?</p> <p>22 A. Well, you'd need to read the whole</p> <p>23 sentence to be complete.</p> <p>24 Q. Okay. Do the authors -- withdrawn.</p>	<p>1 end, at some part of the spectrum away from</p> <p>2 chance? That's basically what it's saying,</p> <p>3 right?</p> <p>4 MR. PARKER: Objection.</p> <p>5 A. No, I think you're reading that</p> <p>6 incorrectly. They're being very careful to</p> <p>7 exactly not say what you're saying.</p> <p>8 BY MR. SLATER:</p> <p>9 Q. You would agree that the Rubio-Tapia</p> <p>10 study showed an association between olmesartan</p> <p>11 and severe sprue-like enteropathy, correct?</p> <p>12 A. No, I would not.</p> <p>13 Q. So you disagree with the authors of</p> <p>14 the study?</p> <p>15 A. No, I think I agree with their</p> <p>16 interpretations, but you do have to look at</p> <p>17 their inclusion criteria. Based on their</p> <p>18 inclusion criteria, you can't speculate whether</p> <p>19 there's an association, because unless there was</p> <p>20 recovery after withdrawal of olmesartan the</p> <p>21 patient was not included in their study. So by</p> <p>22 definition, the study must show in the subgroup</p> <p>23 of patients carefully selected, that those</p> <p>24 patients had an association.</p>

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<p style="text-align: right;">Page 66</p> <p>1 So -- and you can make an analogy with 2 flipping a coin. If every time I flip a coin it 3 turns up heads or tails, but I only show you the 4 versions where it shows up heads, then you could 5 conclude that flipping a coin was associated 6 with turning out heads if you ignore those that 7 turn out tails. 8 That's, in essence, how this study was 9 prepared. It's great as something to make the 10 medical experts aware of, but it doesn't prove 11 association because it's not statistically 12 designed to do that. 13 Q. You would agree it was important for 14 this article to be published so that clinicians 15 would be aware of this potential association, 16 correct? 17 A. Yes. But you should also recognize 18 where it was published. That also tells you 19 something about the importance and impact to the 20 medical literature. 21 MR. SLATER: Move to strike after 22 "yes." 23 Q. Are the Annals of Internal Medicine 24 considered to be a high powered medical journal?</p>	<p style="text-align: right;">Page 68</p> <p>1 not even close. 2 Q. Is it your opinion that I'm naive? 3 A. No. The question is naive. 4 Q. I mean if you think I'm naive, you 5 should say it. 6 A. I think you're probably quite 7 knowledgeable. But I think in that area, your 8 question was naive. 9 Q. Okay. Has the New England Journal of 10 Medicine ever published an article that later 11 had to be corrected because the information 12 communicated turned out to be wrong? 13 A. I'm sure it has. 14 Q. So am I. So let's not be naive, 15 Doctor. 16 A. I don't think that's the same thing. 17 Q. Okay. You've made a comment about 18 where the article was published, the Rubio-Tapia 19 2012 article. Do I understand you to be 20 impugning the value of the Mayo Clinic 21 Proceedings, that journal that it was published 22 in? 23 A. Well, knowing some of the authors 24 here, I would suspect that they would have sent</p>
<p style="text-align: right;">Page 67</p> <p>1 A. Annals of Internal Medicine is a 2 reputable journal. 3 Q. It's considered to be a high powered 4 journal, correct? 5 A. I don't know the impact factor or the 6 citation rate or anything else about it to 7 specifically comment on that, but it's a 8 reputable journal. 9 Do you have those numbers for me? 10 Q. No, I don't. 11 A. Then I don't know. 12 Q. Is the New England Journal of Medicine 13 a high powered journal? 14 A. Yes, it is. 15 Q. Are the Annals of Internal Medicine 16 and the New England Journal of Medicine roughly 17 on the same level? 18 A. Not even close. 19 Q. Okay. 20 A. That's a surprising question. 21 Q. Really? How come it's surprising, 22 Doctor? 23 A. Because it's naive to think that those 24 journals are on par with one another. They're</p>	<p style="text-align: right;">Page 69</p> <p>1 it to a more reputable journal if that option 2 had been available to them. And I'm not sure 3 what -- I have never talked to them, I don't 4 know the track of what this article took, but 5 this is not what you'd call a highly respected 6 journal. It's essentially an internal journal. 7 Q. So you're speculating about why they 8 published the article in that journal, right? 9 You have no idea? 10 A. I'm not speculating. I'm telling you 11 that this is essentially an internal journal 12 with limited stature in the field. And if they 13 felt it was as important a study as you're 14 implying, then I am surprised that they would 15 publish it here. 16 Q. All I'm asking is this. You don't 17 know why Dr. Murray and his co-authors chose to 18 publish the article in the Mayo Clinic 19 Proceedings? You don't know, right? 20 A. It could be for any number of reasons. 21 Q. Look at Page 737 of the article, 22 please, bottom right, Table 3, it says "Clinical 23 Features of Spruelike Enteropathy Associated 24 With Olmesartan."</p>

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<p style="text-align: right;">Page 70</p> <p>1 Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. If a patient meets those criteria, do</p> <p>4 you agree that an association is shown in the</p> <p>5 case of those patients between olmesartan and</p> <p>6 sprue-like enteropathy?</p> <p>7 A. No.</p> <p>8 Q. Are you saying that every patient that</p> <p>9 meets that criteria, it's just a coincidence</p> <p>10 that when they got off the olmesartan that they</p> <p>11 got better?</p> <p>12 A. I'm saying that the title of the table</p> <p>13 says these are features associated with</p> <p>14 olmesartan. They don't say diagnostic of, using</p> <p>15 your words, olmesartan-associated enteropathy.</p> <p>16 So I don't think that you should be used that</p> <p>17 table for the purpose of which it was clearly</p> <p>18 not intended.</p> <p>19 Q. Did I say diagnostic? I didn't say</p> <p>20 that word, Doctor.</p> <p>21 A. You're making a diagnostic conclusion</p> <p>22 in the way you phrased your question. Can we</p> <p>23 read it back?</p> <p>24 Q. I'll ask a different question. I'll</p>	<p style="text-align: right;">Page 72</p> <p>1 MR. PARKER: Hold on. Objection.</p> <p>2 Argumentative. You can ask your question again.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. Doctor, look at Table 3, the title,</p> <p>5 "Clinical Features of Spruelike Enteropathy</p> <p>6 Associated With Olmesartan."</p> <p>7 Do you see that?</p> <p>8 A. Yes, I do.</p> <p>9 Q. And you see the list of clinical</p> <p>10 features?</p> <p>11 A. Yes, I do.</p> <p>12 Q. For a patient that has those clinical</p> <p>13 features, do you agree that that is a patient in</p> <p>14 which those clinical features are associated</p> <p>15 with olmesartan?</p> <p>16 A. That's really kind of circular logic</p> <p>17 the way you phrased it. Do you want to try a</p> <p>18 fourth time?</p> <p>19 Q. No. I want you to answer the</p> <p>20 question.</p> <p>21 A. It's circular logic, so I have to say</p> <p>22 no.</p> <p>23 Q. Is there an association that has been</p> <p>24 established in the literature for at least the</p>
<p style="text-align: right;">Page 71</p> <p>1 ask it again. I don't need to read it back.</p> <p>2 Here's the question.</p> <p>3 If a patient meets the criteria in</p> <p>4 Table 3, do you agree that in those cases those</p> <p>5 clinical features would be associated with the</p> <p>6 use of olmesartan?</p> <p>7 A. First, there are no criteria listed in</p> <p>8 Table 3. There are features listed. And</p> <p>9 nowhere does it say that meeting these -- having</p> <p>10 these features confirms that the patient has a</p> <p>11 specific diagnosis, in this case you're saying</p> <p>12 the diagnosis would be olmesartan-associated</p> <p>13 enteropathy.</p> <p>14 MR. SLATER: Move to strike.</p> <p>15 Q. I haven't used the word diagnosis,</p> <p>16 Doctor, so I just don't understand why you keep</p> <p>17 saying it. I'm asking about association.</p> <p>18 A. You're saying does that -- can we read</p> <p>19 the question back?</p> <p>20 Q. No, we're not going to read the</p> <p>21 question back. I'm going to ask it again to</p> <p>22 you. I'm not going to use the word diagnosis, I</p> <p>23 promise.</p> <p>24 A. I know, but you're implying --</p>	<p style="text-align: right;">Page 73</p> <p>1 subset of patients who would meet this clinical</p> <p>2 criteria?</p> <p>3 A. No.</p> <p>4 Q. Are there published studies in</p> <p>5 reputable medical journals where they do</p> <p>6 conclude that the association exists for</p> <p>7 patients that have this type of clinical</p> <p>8 criteria?</p> <p>9 A. If you exclude and make a very</p> <p>10 carefully selected subset, yes, but only in that</p> <p>11 context.</p> <p>12 Q. The very carefully selected subset</p> <p>13 would be those patients that fit this criteria</p> <p>14 that's listed as clinical features, correct?</p> <p>15 A. And others. This is not exhaustive.</p> <p>16 Q. Other clinical features?</p> <p>17 A. Yes, this is not exhaustive and is not</p> <p>18 sufficient to make that conclusion.</p> <p>19 Q. What other clinical features would you</p> <p>20 add to this table to make it complete?</p> <p>21 A. It depends if you're asking about</p> <p>22 associated with or caused by. Are you asking</p> <p>23 about associated with?</p> <p>24 Q. Let's start with associated with.</p>

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<p style="text-align: right;">Page 74</p> <p>1 A. Associated with, you would like to see 2 some evidence of a controlled rechallenge that 3 really told you that it was due to olmesartan, 4 or at least a highly controlled dechallenge in 5 which you could say it was associated. 6 Obviously a dechallenge would never be 7 sufficient in a single case for making that 8 conclusion of causation, but it probably could 9 be sufficient for saying in that patient it's 10 associated and maybe we should just sort of not 11 worry about it and give that patient some other 12 drug. 13 Q. There are some highly controlled 14 dechallenges in the case reports published in 15 the literature, right? 16 A. I don't believe so. 17 Q. Okay. If you have a patient who -- 18 let me rephrase. 19 I'm going to give you a hypothetical 20 patient and ask you a question about the 21 patient. Okay? 22 A. Okay. 23 Q. If you have a patient who is taking 24 olmesartan for more than two years, and more</p>	<p style="text-align: right;">Page 76</p> <p>1 diarrhea, the weight loss, and the villous 2 atrophy? 3 A. Were they IgA deficient? 4 Q. Why would you want to know that? 5 A. If they were IgA deficient, they would 6 have some chance of having seronegative celiac 7 disease. 8 Q. Okay. Let's assume that they are IgA 9 deficient, however, the patient continued to eat 10 gluten both before, during, and after the use of 11 olmesartan, and that had no impact on the 12 symptoms, meaning the patient had no chronic 13 diarrhea, weight loss, or villous atrophy before 14 taking the olmesartan, and after stopping the 15 olmesartan when the resolution occurred the 16 patient was continuing to eat gluten without any 17 restrictions, with that addition to the 18 hypothetical, the most likely cause would be the 19 olmesartan, correct? 20 A. What other agents are they taking? 21 Q. No other medications. 22 A. Do they have any comorbidities? 23 Q. No comorbidities. 24 A. Do they have any evidence of vascular</p>
<p style="text-align: right;">Page 75</p> <p>1 than two years after starting to take olmesartan 2 the patient develops chronic diarrhea, weight 3 loss greater than 10 pounds, villous atrophy, 4 the patient tests negative on celiac serologies, 5 the patient stops taking the olmesartan, and 6 over the course of time after that, with no 7 other change in any medications or any other 8 changes in diet, the patient's clinical symptoms 9 of chronic diarrhea and weight loss resolve, and 10 the villous atrophy resolves. Okay? That's my 11 patient. Do you understand? 12 A. Yes. 13 Q. In that patient, the most likely cause 14 of the chronic diarrhea, the weight loss and the 15 villous atrophy would be the olmesartan, 16 correct? 17 A. I would need to know more about the 18 patient. 19 Q. What else would you need to know? 20 A. Well, I can give you a hypothetical. 21 Q. No, no, no. I have a hypothetical. 22 What else would you need to know about that 23 patient to tell me whether or not the olmesartan 24 is the most likely cause of the chronic</p>	<p style="text-align: right;">Page 77</p> <p>1 disease? 2 Q. No evidence of vascular disease, other 3 than if you want to term hypertension vascular 4 disease. They have hypertension, that's why 5 they took the olmesartan. 6 A. Do they have -- have they had 7 autoimmune serologies? 8 Q. Yes. They were negative. 9 A. Have you done O&P? 10 Q. What is an O&P? 11 A. Ova and parasite test. 12 Q. Yes, they were negative. And stool 13 studies were done, which were negative. 14 A. Okay. And they didn't take any other 15 drugs at the time the olmesartan was 16 discontinued? 17 Q. No. 18 A. And they were on a controlled diet 19 that was identical? 20 Q. They made no changes to their diet, 21 freely ate gluten the entire time. 22 A. Anything else? 23 Q. No. 24 A. I mean, was it a controlled diet that</p>

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<p style="text-align: right;">Page 78</p> <p>1 was the same or not?</p> <p>2 Q. Well, I don't know what you mean by</p> <p>3 the same. You mean did they eat three meals a</p> <p>4 day that were the exact same food? There was no</p> <p>5 -- let me answer the question. There was no</p> <p>6 alteration in the diet from before using the</p> <p>7 olmesartan, during the olmesartan, and after the</p> <p>8 olmesartan, whatever the person ate generally</p> <p>9 did not change.</p> <p>10 A. In that patient, under that setting, I</p> <p>11 would say let's find you a different</p> <p>12 antihypertensive, there are reports of this in</p> <p>13 patients taking olmesartan, and if you stay</p> <p>14 healthy on another antihypertensive we'll call</p> <p>15 it a win. I don't think you can necessarily</p> <p>16 conclude causation.</p> <p>17 Q. More likely than not that patient, the</p> <p>18 cause of the chronic diarrhea, the weight loss,</p> <p>19 and the villous atrophy was the olmesartan,</p> <p>20 that's the most likely cause, correct?</p> <p>21 A. Well, I would draw a direct analogy to</p> <p>22 celiac disease and say no.</p> <p>23 Q. In that patient was the most likely</p> <p>24 cause of the chronic diarrhea, the weight loss,</p>	<p style="text-align: right;">Page 80</p> <p>1 differential diagnosis in that hypothetical as</p> <p>2 we developed it?</p> <p>3 A. To put that at the top of your</p> <p>4 differential diagnosis you'd have to know that</p> <p>5 it was a cause. We don't know that.</p> <p>6 Q. Olmesartan would be on the</p> <p>7 differential diagnosis for that patient,</p> <p>8 correct?</p> <p>9 A. You would have to think about</p> <p>10 olmesartan based on case reports and labels, but</p> <p>11 not based on scientifically rigorous fact.</p> <p>12 MR. SLATER: Move to strike from "but"</p> <p>13 forward.</p> <p>14 Q. Doctor, it's a very simple question,</p> <p>15 yes or no. Would olmesartan be on the</p> <p>16 differential diagnosis as the cause of this</p> <p>17 patient's clinical presentation as we described</p> <p>18 it?</p> <p>19 MR. PARKER: Objection.</p> <p>20 A. No.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. What -- now you're saying olmesartan</p> <p>23 is not on the differential diagnosis? You just</p> <p>24 said a question ago it is on the differential</p>
<p style="text-align: right;">Page 79</p> <p>1 and the villous atrophy, tell me what the most</p> <p>2 likely cause was. If it's not olmesartan, what</p> <p>3 is it?</p> <p>4 A. I can't name a specific cause. But</p> <p>5 what I can tell you is that, for example, in</p> <p>6 celiac disease, response to a gluten-free diet</p> <p>7 is insufficient to conclude that it's celiac</p> <p>8 disease. I don't know how withdrawing the drug,</p> <p>9 which would be the same as withdrawing the</p> <p>10 gluten from the diet, is sufficient then to</p> <p>11 conclude that it must be due to the drug.</p> <p>12 MR. SLATER: Move to strike after</p> <p>13 "but."</p> <p>14 Q. Doctor, have you ever been involved in</p> <p>15 the actual diagnosis of a patient that actually</p> <p>16 had a gastrointestinal disorder where a</p> <p>17 differential diagnosis was used?</p> <p>18 A. Of course.</p> <p>19 Q. For the patient that we have described</p> <p>20 in this hypothetical, olmesartan as a cause</p> <p>21 would be at the very top of the differential</p> <p>22 diagnosis, correct?</p> <p>23 A. I don't think it could be.</p> <p>24 Q. What else would be on that</p>	<p style="text-align: right;">Page 81</p> <p>1 diagnosis, you realize that, right?</p> <p>2 MR. PARKER: Objection.</p> <p>3 A. You realize you asked the question</p> <p>4 differently.</p> <p>5 BY MR. SLATER:</p> <p>6 Q. Look, you know what? There's a</p> <p>7 transcript and you're going to testify in a</p> <p>8 courtroom, so, you know, every answer you give</p> <p>9 you own. You know that, right?</p> <p>10 MR. PARKER: And you own your</p> <p>11 questions. Let's go on, Adam.</p> <p>12 MR. SLATER: Believe me, I do.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. Let me ask you this, Doctor. The</p> <p>15 answer you just gave to this hypothetical, would</p> <p>16 you be comfortable if I took this video and put</p> <p>17 it on YouTube for all your colleagues around the</p> <p>18 United States to see that testimony?</p> <p>19 A. Absolutely.</p> <p>20 Q. Okay. You would agree with me that</p> <p>21 there have been some patients who have developed</p> <p>22 what is described in the Rubio-Tapia article as</p> <p>23 severe sprue-like enteropathy caused by</p> <p>24 olmesartan? There are some patients in the</p>

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<p style="text-align: right;">Page 82</p> <p>1 world where that has happened, you would agree</p> <p>2 with that, correct?</p> <p>3 A. No.</p> <p>4 Q. So all of these reports, the case</p> <p>5 reports and all the other studies, in every one</p> <p>6 of those patients it was a coincidence that the</p> <p>7 patient was taking olmesartan, got off</p> <p>8 olmesartan, their use of olmesartan in every one</p> <p>9 of those cases was coincidental and had nothing</p> <p>10 to do with their illness, is that your</p> <p>11 testimony?</p> <p>12 A. My previous response was in response</p> <p>13 to your question. We can ask the court reporter</p> <p>14 to read back the question if you'd like.</p> <p>15 Q. I just asked you a new question.</p> <p>16 Is that your testimony?</p> <p>17 A. Can you repeat that question somebody?</p> <p>18 Q. She'll read it back to you.</p> <p>19 (Whereupon, the reporter read back the</p> <p>20 pending question.)</p> <p>21 A. There's not sufficient evidence to</p> <p>22 conclude either way.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. So you don't have an opinion one way</p>	<p style="text-align: right;">Page 84</p> <p>1 causal association.</p> <p>2 Q. Let me ask you this question.</p> <p>3 Do you understand what reasonable</p> <p>4 degree of medical certainty means?</p> <p>5 A. Yes, I do.</p> <p>6 Q. What do you think it means?</p> <p>7 A. It means more likely than not.</p> <p>8 Q. Okay. Are you aware that there are</p> <p>9 physicians at some of -- at the top celiac</p> <p>10 centers in the United States who have diagnosed</p> <p>11 patients with sprue-like enteropathy caused by</p> <p>12 olmesartan? Are you aware that that has been</p> <p>13 happening in the United States the last five</p> <p>14 years?</p> <p>15 A. I'm aware that patients in those</p> <p>16 sentence have -- some patients have done well</p> <p>17 when olmesartan was withdrawn.</p> <p>18 Q. For those patients, you realize they</p> <p>19 were diagnosed with, we can call it sprue-like</p> <p>20 enteropathy or olmesartan-associated</p> <p>21 enteropathy, you realize that was their</p> <p>22 diagnosis at the top celiac centers in the</p> <p>23 United States for some patients? Do you realize</p> <p>24 that? Yes or no.</p>
<p style="text-align: right;">Page 83</p> <p>1 or the other on that question?</p> <p>2 A. No, I do have an opinion.</p> <p>3 Q. You just said the information -- the</p> <p>4 evidence is not sufficient one way or the other.</p> <p>5 That means you can't state to a reasonable</p> <p>6 degree of medical certainty one way or the other</p> <p>7 on that question, right?</p> <p>8 MR. PARKER: Objection.</p> <p>9 A. You asked me if I believed it was</p> <p>10 coincidence, and I said there was not enough</p> <p>11 information to conclude whether or not it was a</p> <p>12 coincidence.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. Okay. If it was not a coincidence,</p> <p>15 then that would mean that in some cases there</p> <p>16 was a causal relationship between the olmesartan</p> <p>17 and the illness, right?</p> <p>18 A. If that were true, and it was not --</p> <p>19 it was shown rigorously not to be a coincidence,</p> <p>20 that would mean in those specific patients there</p> <p>21 would be an association, yes.</p> <p>22 Q. It would be a causal association,</p> <p>23 right?</p> <p>24 A. I think you need more to conclude a</p>	<p style="text-align: right;">Page 85</p> <p>1 A. Yes, that's a label that's been put on</p> <p>2 them, absolutely.</p> <p>3 Q. You're not telling this jury that you</p> <p>4 think that every single time a patient got off</p> <p>5 olmesartan and got better, in the absence of</p> <p>6 changing any of their other medications or</p> <p>7 changing their diet in any other way, you're not</p> <p>8 saying that you think it was coincidence that</p> <p>9 they got better after taking off -- stopping the</p> <p>10 olmesartan in every one of those cases? You're</p> <p>11 not saying that, are you?</p> <p>12 A. I don't think I've seen documentation</p> <p>13 of the case you just described.</p> <p>14 Q. You haven't seen documentation of a</p> <p>15 case where a patient got off of olmesartan and</p> <p>16 got better where their other medications weren't</p> <p>17 changed and their diet wasn't changed?</p> <p>18 A. I think the reports that we've seen</p> <p>19 are pretty superficial in those descriptions,</p> <p>20 and there really isn't sufficient data to know</p> <p>21 that.</p> <p>22 MR. SLATER: Why don't we do this.</p> <p>23 Why don't we take a break for about 5 or</p> <p>24 10 minutes.</p>

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<p style="text-align: right;">Page 86</p> <p>1 MR. PARKER: Okay. We've got to</p> <p>2 refill the water jug anyway, I've been pretty</p> <p>3 much consuming all of it.</p> <p>4 MR. SLATER: Let's go off the video,</p> <p>5 please.</p> <p>6 THE VIDEOGRAPHER: Going off the</p> <p>7 record. The time is 10:42.</p> <p>8 (Whereupon, a recess was taken.)</p> <p>9 (Whereupon, Turner Exhibit Number 8,</p> <p>10 Printout from Brigham & Women's</p> <p>11 Hospital website on Olmesartan</p> <p>12 tablets, was marked for</p> <p>13 identification.)</p> <p>14 THE VIDEOGRAPHER: Back on the record.</p> <p>15 The time is 10:55.</p> <p>16 BY MR. SLATER:</p> <p>17 Q. Doctor, I just provided you what we've</p> <p>18 marked as Exhibit 9, and I can tell you I</p> <p>19 printed this off the website at Brigham &</p> <p>20 Women's Hospital two days ago. You can see it</p> <p>21 in the top left, February 14, 2017.</p> <p>22 MR. FOUNDAS: Adam, it's actually</p> <p>23 Exhibit 8.</p> <p>24 MR. SLATER: Oh, it's Exhibit 8?</p>	<p style="text-align: right;">Page 88</p> <p>1 Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. And then it says, "Side effects that</p> <p>4 you should report to your doctor or health care</p> <p>5 professional as soon as possible," and then</p> <p>6 there's a list.</p> <p>7 Do you see that list?</p> <p>8 A. Yes, I do.</p> <p>9 Q. And you see that list includes</p> <p>10 diarrhea, vomiting, and weight loss.</p> <p>11 Do you see that?</p> <p>12 A. I think this is essentially the same</p> <p>13 as the label on the bottle, is that right?</p> <p>14 MR. SLATER: Move to strike.</p> <p>15 Q. Do you see what I just pointed out, it</p> <p>16 says diarrhea, vomiting, and weight loss?</p> <p>17 A. Yes.</p> <p>18 Q. And you agree that diarrhea, vomiting,</p> <p>19 and weight loss are side effects that a patient</p> <p>20 may experience from receiving olmesartan,</p> <p>21 correct?</p> <p>22 A. It's possible.</p> <p>23 Q. You agree that in some patients that</p> <p>24 occurs, correct?</p>
<p style="text-align: right;">Page 87</p> <p>1 MR. FOUNDAS: Yes.</p> <p>2 MR. SLATER: I'll start over.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. Doctor, do you see in front of you</p> <p>5 Exhibit 8?</p> <p>6 A. You're breaking up a lot.</p> <p>7 Q. Doctor, do you see in front of you</p> <p>8 Exhibit 8?</p> <p>9 A. Yes, I do.</p> <p>10 Q. This is a document I printed off the</p> <p>11 Brigham & Women's Hospital website, you can see</p> <p>12 in the top left February 14, 2017, from the</p> <p>13 health library at your hospital.</p> <p>14 Do you see that?</p> <p>15 A. Yes, I do.</p> <p>16 Q. Have you seen this before?</p> <p>17 A. I have not.</p> <p>18 Q. And this is a page regarding</p> <p>19 olmesartan tablets.</p> <p>20 Do you see that?</p> <p>21 A. Yes, I see that.</p> <p>22 Q. And if you go down a few lines it</p> <p>23 says, "What side effects may I notice from</p> <p>24 receiving this medicine?"</p>	<p style="text-align: right;">Page 89</p> <p>1 A. No. We've been over that.</p> <p>2 Q. So Brigham & Women's when they say</p> <p>3 that these side effects can occur as a result of</p> <p>4 the patient taking the medication, you disagree</p> <p>5 with the hospital you work at?</p> <p>6 MR. PARKER: Objection.</p> <p>7 A. I don't think the document says that</p> <p>8 these occur.</p> <p>9 BY MR. SLATER:</p> <p>10 Q. So you think they're listing random</p> <p>11 side effects there that they don't -- that your</p> <p>12 hospital doesn't think occur from olmesartan?</p> <p>13 That wouldn't seem to make sense, would it?</p> <p>14 MR. PARKER: Objection.</p> <p>15 A. No. They're protecting themselves</p> <p>16 from legal challenge and from lawsuits by</p> <p>17 reproducing what I presume is on the label. I</p> <p>18 haven't memorized the olmesartan label, but I'm</p> <p>19 guessing this is pretty close to what the label</p> <p>20 represents.</p> <p>21 MR. SLATER: Move to strike.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. The label for olmesartan and the</p> <p>24 information about sprue-like enteropathy is in</p>

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<p style="text-align: right;">Page 90</p> <p>1 the label in part because the FDA thinks that 2 language is necessary, right? 3 A. Right. 4 Q. Do you know if Daiichi objected when 5 the FDA asked them to put a warning for 6 sprue-like enteropathy in the label? Do you 7 know whether Daiichi objected to that? 8 A. No, I don't know. 9 Q. Do you know what warnings Daiichi 10 wrote internally before the FDA sent them the 11 language regarding Daiichi's internal assessment 12 of what the warning should say? 13 A. No. 14 Q. Would you expect that Daiichi, the 15 manufacturer, the seller of the drug would have 16 extensive knowledge about these side effects 17 caused by the drug? 18 A. I would imagine that they've done 19 careful studies, yes, and know everything they 20 can know. 21 Q. Do you know what the term drug -- 22 rephrase. 23 Do you know what the phrase olmesartan 24 induced enteropathy means?</p>	<p style="text-align: right;">Page 92</p> <p>1 A. I would say that that's what's implied 2 by those terms. 3 Q. Well, when you say it's implied, 4 that's what it means, right? 5 MR. PARKER: Objection. 6 A. It's what's implied. 7 BY MR. SLATER: 8 Q. Well, it's implied, so it's not clear 9 to you what the word induced means? You don't 10 understand that word? Should we pull out a 11 dictionary, or Wikipedia or something? 12 MR. PARKER: Objection. 13 A. Sure, let's get a dictionary. That's 14 okay. 15 MR. PARKER: Come on, guys, let's move 16 on. 17 BY MR. SLATER: 18 Q. Let's do this. You don't know what 19 induced means, is that what you're telling me? 20 You know what it's implied to mean, but you 21 don't know what it actually means, that's what 22 you're telling the judge and the jury, right? 23 A. No. I know what induced means, and I 24 don't think it means exactly the same thing as</p>
<p style="text-align: right;">Page 91</p> <p>1 A. I've heard people use that rarely. 2 Q. Do you know what it means? 3 A. I know what they're implying, yes. 4 Q. Doctor, olmesartan induced enteropathy 5 means sprue-like enteropathy caused by 6 olmesartan, correct? 7 MR. PARKER: Objection. 8 A. That's the implication. 9 BY MR. SLATER: 10 Q. That's what it means, right? 11 MR. PARKER: Objection. 12 A. I answered you, right? 13 BY MR. SLATER: 14 Q. I don't think you did. I didn't ask 15 you if it's implied. It's a very simple 16 question. 17 Olmesartan induced enteropathy means 18 enteropathy caused by olmesartan, correct? 19 A. If it meant exactly that, why don't 20 they just say enteropathy caused by olmesartan? 21 MR. SLATER: Move to strike. 22 Q. Doctor, I'm not here to argue with 23 you. It's a simple yes or no question. 24 Is that what the terms mean?</p>	<p style="text-align: right;">Page 93</p> <p>1 caused. 2 Q. Do you know what the head of 3 pharmacovigilance for Daiichi in the United 4 States said when I asked him if olmesartan 5 induced enteropathy means enteropathy caused by 6 olmesartan? Do you know what he said? 7 A. No, I don't. 8 Q. Would you be interested in knowing 9 what he said? 10 A. Sure. 11 Q. He said it means caused by. Is that 12 helpful to you in defining that term? 13 MR. PARKER: Objection. 14 A. Then that's what it means to him. But 15 I interpret induced and caused to be subtly 16 different. 17 Is he a native English speaker? Maybe 18 he doesn't get the vocabulary quite right. 19 BY MR. SLATER: 20 Q. I guess you don't know who he is, so 21 we'll keep you in the dark on that one. 22 A. Okay. 23 Q. Do you know if Daiichi uses the term 24 olmesartan induced enteropathy in their internal</p>

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<p style="text-align: right;">Page 94</p> <p>1 documents to describe this condition that we're 2 talking about? 3 A. I don't believe I saw it in the 4 documents that I saw. 5 Q. Would it be helpful to you to know 6 that -- rephrase. 7 If, in fact, Daiichi in its own 8 internal documents refers to the condition as 9 olmesartan induced enteropathy, that would be 10 significant to you, since they presumably are 11 experts regarding the side effects caused by 12 their drug, right? 13 MR. PARKER: Objection. 14 A. It depends. It would certainly be 15 something to be aware of, but it wouldn't be the 16 only factor in my thinking, because then I would 17 be just accepting their conclusion based on data 18 I haven't seen. So it would really depend on 19 why they were making that conclusion. 20 BY MR. SLATER: 21 Q. If there are physicians employed by 22 Daiichi who found in reviewing adverse event 23 reports that gastrointestinal illness 24 representing sprue-like enteropathy in terms of</p>	<p style="text-align: right;">Page 96</p> <p>1 talks about severe diarrhea and weight loss, 2 correct? 3 A. Can we -- let's be specific. Do we 4 have a copy of the label? 5 Q. No, we don't. You don't know if the 6 label says that? 7 A. I don't know the specific words. You 8 seem to be very fond of slipping in words that 9 change nuanced meanings, so I'm cautious about 10 that. I don't know the exact words on the label 11 by memory. 12 Q. Is there a warning in the label for 13 olmesartan that warns of sprue-like enteropathy? 14 A. Let me see if I have a copy of the 15 label. 16 (Witness reviewing document.) 17 BY MR. SLATER: 18 Q. You don't know if the word sprue-like 19 enteropathy appears in the label for the 20 olmesartan drugs? Doctor, you don't know if 21 that term appears in the label? 22 A. I'm looking for the label. 23 Q. I'm asking you, without looking at it 24 you don't know if that term appears in the</p>
<p style="text-align: right;">Page 95</p> <p>1 the collection of symptoms was caused by 2 olmesartan in some patients, that would be very 3 significant to you, correct? 4 A. Sure, I'd very much like to see those 5 data. 6 Q. Nobody showed it to you, right? 7 A. No. 8 Q. And, in fact, if you were to be shown 9 that data, that could change your opinions in 10 that case, correct? 11 A. It depends on what the data were, but 12 certainly. 13 Q. Coming back to Exhibit 8, I think you 14 said that you believe that the listing of 15 diarrhea, vomiting, and weight loss as potential 16 side effects with olmesartan, I think you said 17 that's your understanding of essentially what 18 the label says about sprue-like enteropathy, 19 correct? 20 A. No. I said I think that this 21 information generally reproduces what's on the 22 label. 23 Q. And the label for olmesartan includes 24 a warning about sprue-like enteropathy which</p>	<p style="text-align: right;">Page 97</p> <p>1 label? It's a yes or no question before you 2 pull the label out. 3 A. I would like to -- 4 Q. I'm instructing you not to look at the 5 label to answer this question. 6 MR. TURNER: You can't instruct him 7 not to look at the label. You've asked him 8 three times. 9 Doctor, do the best you can in 10 answering the question. 11 You can't instruct him what he can and 12 can't do, Adam. 13 MR. SLATER: I can. 14 BY MR. SLATER: 15 Q. Doctor, without looking at the label, 16 do you know whether the term sprue-like 17 enteropathy appears in the label for the 18 olmesartan drugs? 19 A. I believe it likely does, but I'm not 20 entirely sure that it's that exact phraseology, 21 and that's why I'd like to check and be precise. 22 Q. Wonderful. If you have the label 23 there, pull it out. 24 (Witness reviewing documents.)</p>

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<p style="text-align: right;">Page 98</p> <p>1 BY MR. SLATER:</p> <p>2 Q. Did you find it, Doctor?</p> <p>3 A. No, I'm not finding an actual reprint</p> <p>4 of the label, I'm sorry.</p> <p>5 Q. You have the FDA safety notification</p> <p>6 right in front of you, right?</p> <p>7 A. Yes, I do.</p> <p>8 Q. Right in the beginning it says that</p> <p>9 "Olmesartan can cause sprue-like enteropathy,"</p> <p>10 right? Doctor, the very first paragraph, do you</p> <p>11 see it?</p> <p>12 A. Yes. And I think they're using the</p> <p>13 regulatory phraseology, so they're saying "can"</p> <p>14 as in it's possible that they caused these</p> <p>15 intestinal problems.</p> <p>16 Q. Doctor, it says right on the drug</p> <p>17 safety communication, July 3, 2013, "The US Food</p> <p>18 and Drug Administration (FDA) is warning that</p> <p>19 the blood pressure drug olmesartan medoxomil</p> <p>20 (marketed as Benicar, Benicar HCT, Azor,</p> <p>21 Tribenzor, and generics) can cause intestinal</p> <p>22 problems known as sprue-like enteropathy."</p> <p>23 That's the words, right?</p> <p>24 A. That's the words.</p>	<p style="text-align: right;">Page 100</p> <p>1 A. I don't know this document, but my</p> <p>2 impression is that this is computer generated</p> <p>3 from some library at the FDA.</p> <p>4 MR. SLATER: Move to strike from "but"</p> <p>5 forward.</p> <p>6 Q. Diarrhea, vomiting, and weight loss</p> <p>7 are features of olmesartan-associated</p> <p>8 enteropathy, correct?</p> <p>9 A. They have been listed in articles as</p> <p>10 under that heading.</p> <p>11 Q. You mentioned rechallenges earlier.</p> <p>12 Remember you mentioned rechallenges?</p> <p>13 A. Yes.</p> <p>14 Q. Were there a controlled rechallenge</p> <p>15 and the person's symptoms recur when that</p> <p>16 occurs, that is strong evidence of causation,</p> <p>17 correct?</p> <p>18 A. In a randomized clinical trial</p> <p>19 setting, absolutely.</p> <p>20 Q. Are you saying the only rechallenge</p> <p>21 that you would ever recognize as being</p> <p>22 legitimate would be one that occurs in a</p> <p>23 randomized controlled trial?</p> <p>24 A. It depends on what you're asking the</p>
<p style="text-align: right;">Page 99</p> <p>1 Q. Do you disagree with the FDA?</p> <p>2 A. No.</p> <p>3 Q. Now, going to Exhibit 8, Brigham &</p> <p>4 Women's Hospital is telling people who want to</p> <p>5 read their health library that side effects that</p> <p>6 patients can suffer as a result of taking</p> <p>7 olmesartan include diarrhea, vomiting, and</p> <p>8 weight loss, that's what your institution is</p> <p>9 telling patients, correct?</p> <p>10 A. Yes.</p> <p>11 Q. And that's truthful -- let me</p> <p>12 rephrase.</p> <p>13 And that is truthful information,</p> <p>14 correct?</p> <p>15 A. They're saying what side effects may I</p> <p>16 notice from receiving this medication. So</p> <p>17 they're listing that as a possible side effect</p> <p>18 that you should report to your doctor or health</p> <p>19 care professional.</p> <p>20 Q. The reason Brigham & Women's provides</p> <p>21 possible side effects here in that library is so</p> <p>22 patients will be aware of side effects that your</p> <p>23 institution thinks can occur in some patients</p> <p>24 due to taking the drug, right?</p>	<p style="text-align: right;">Page 101</p> <p>1 question -- what question you're asking that to</p> <p>2 inform.</p> <p>3 Q. If a physician or physicians are</p> <p>4 treating a patient, they rechallenge the patient</p> <p>5 with olmesartan without any other changes to</p> <p>6 what medication the patient is taking or any</p> <p>7 other changes to diet, and the symptoms of</p> <p>8 sprue-like enteropathy happen again on</p> <p>9 rechallenge, that is strong evidence of</p> <p>10 causation, correct?</p> <p>11 THE VIDEOGRAPHER: Mr. Slater, this is</p> <p>12 the videographer speaking. That question broke</p> <p>13 up a number of times.</p> <p>14 MR. SLATER: All right. I'll ask it</p> <p>15 again.</p> <p>16 Q. Where a physician is treating a</p> <p>17 patient, the patient has been taken off of</p> <p>18 olmesartan and their symptoms of sprue-like</p> <p>19 enteropathy stopped, and then the doctor puts</p> <p>20 the patient back on olmesartan, and the symptoms</p> <p>21 happen again where there were no other changes</p> <p>22 to medication and no other changes to diet, that</p> <p>23 positive rechallenge is strong evidence of</p> <p>24 causation, correct?</p>

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<p>1 A. There's more details that I would 2 need. 3 Q. Based on my question, that is strong 4 evidence of causation, correct? 5 A. No. 6 Q. There may be other -- hang on. There 7 may be other evidence that you may look at also, 8 but that rechallenge with recurrence of symptoms 9 is strong evidence in and of itself of 10 causation, correct? 11 A. With the limited data you provided, my 12 answer is no. 13 Q. What other data do you need on that 14 question? 15 A. Was there a repeat biopsy. 16 Q. What else do you need to know? 17 A. Was the patient -- were there any 18 other health conditions at the time. 19 Q. What else do you need to know? 20 A. Was there a control. 21 Q. What else do you need to know? 22 A. Again, you know, we're coming back to 23 what are you trying to ask. Are you trying to 24 ask if it's an evidence of causation, or are you</p>	<p>1 (Whereupon, Turner Exhibit Number 9, 2 Gallivan and Brown letter to the 3 editor titled Olmesartan induced 4 enterocolitis, was marked for 5 identification.) 6 BY MR. SLATER: 7 Q. Okay. Doctor, I've just handed you or 8 we've just handed you Exhibit 9, and that's a 9 case report that was authored by Dr. Gallivan 10 and Brown in 2014, and that appears on the list 11 of literature you cite in your report, correct? 12 A. I cite it. I wouldn't call it a case 13 report. It's not. 14 Q. What is it? 15 A. It's a letter to the editor. It's in 16 the correspondence section of the journal. 17 Q. You cite this in your report, correct? 18 A. Yes. 19 Q. Let's look at it. I want to look at 20 this case report. First of all, let me ask you 21 this question. 22 Are you familiar with this document? 23 A. Yes, I am. 24 Q. And if you look at what is reported,</p>
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<p>1 trying to ask how to manage the patient? 2 Q. I'm talking about evidence of 3 causation. 4 A. That's a much higher standard than how 5 to best manage the patient. People do 6 therapeutic trials all the time, and if they 7 work out they say it's working for the patient, 8 I'm happy for them, let's go with that. That's 9 not evidence of causation. 10 So in this case I would say that your 11 sort of rechallenge, you know, if the patient 12 got sick within minutes of taking the tablet, 13 I'd say, well, that's completely inconsistent 14 with anything meaningful in the literature, so 15 no, sorry. If the patient got sick three years 16 after starting to take olmesartan again, no, 17 that's not consistent. 18 So you really are not sufficiently 19 detailed for me to answer that question. 20 MR. SLATER: Let's look at document 21 number three, if we could. Not Exhibit 3. 22 23 24</p>	<p>1 it talks about "a 78-year-old woman with a 2 clinical history of hypertension, 3 gastroesophageal reflux disease, 4 hypercholesterolemia and osteoporosis, who had 5 been prescribed olmesartan for four years," 6 right? 7 A. Right. 8 Q. It lists her regular medications, 9 right? 10 A. Right. 11 Q. "There was no history of recent use of 12 a nonsteroidal anti-inflammatory medication," 13 correct? 14 A. Right. 15 Q. "Over the past four months she had 16 experienced severe watery diarrhea which 17 resulted in three hospital admissions, including 18 an ICU admission for acute renal failure 19 secondary to dehydration," correct? 20 A. Correct. 21 Q. She had upper endoscopy and 22 colonoscopy, and "biopsies revealed mild villous 23 blunting in the proximal small intestine with 24 intraepithelial lymphocytosis and lamina propria</p>

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<p style="text-align: right;">Page 106</p> <p>1 inflammation," correct?</p> <p>2 A. Correct.</p> <p>3 Q. If you go further into the next column</p> <p>4 about halfway down, it says "Serum tissue</p> <p>5 transglutaminase antibodies were negative and</p> <p>6 the clinical setting did not support an</p> <p>7 autoimmune enteropathy or immunodeficiency</p> <p>8 syndrome," correct?</p> <p>9 A. Correct.</p> <p>10 Q. "Withdrawal of olmesartan and</p> <p>11 atorvastatin with implementation of total</p> <p>12 parenteral nutrition and oral budesonide</p> <p>13 produced resolution of diarrhea," correct?</p> <p>14 A. Correct.</p> <p>15 Q. "On selectively recommencing only</p> <p>16 olmesartan and oral intake, the diarrhea</p> <p>17 returned," correct?</p> <p>18 A. Correct.</p> <p>19 Q. That is a rechallenge, correct?</p> <p>20 A. That's an uncontrolled rechallenge.</p> <p>21 Q. It's a rechallenge that was overseen</p> <p>22 and conducted by physicians treating the</p> <p>23 patient, correct?</p> <p>24 A. Where does it say that?</p>	<p style="text-align: right;">Page 108</p> <p>1 Oral intake --</p> <p>2 Q. Have I asked you if it's controlled?</p> <p>3 MR. PARKER: Will you let him finish,</p> <p>4 Adam, please?</p> <p>5 MR. SLATER: He's wasting my time.</p> <p>6 MR. PARKER: And you're wasting our</p> <p>7 time.</p> <p>8 BY MR. SLATER:</p> <p>9 Q. Don't tell me whether it's controlled,</p> <p>10 Doctor.</p> <p>11 MR. PARKER: You're wasting everyone's</p> <p>12 time by not letting the witness answer. You</p> <p>13 don't like his answer, that's fine, move on.</p> <p>14 MR. SLATER: Maybe you should instruct</p> <p>15 your answer to stop talking about whether it's</p> <p>16 controlled when I'm not asking about it and</p> <p>17 burning -- and wasting our time.</p> <p>18 MR. PARKER: Instruct my answer? I</p> <p>19 don't understand your comment.</p> <p>20 MR. SLATER: You should instruct your</p> <p>21 witness to be responsive.</p> <p>22 MR. PARKER: He is responsive. Let's</p> <p>23 go on, gentlemen. Gentlemen, let's go on.</p> <p>24 MR. SLATER: I'm trying to. You keep</p>
<p style="text-align: right;">Page 107</p> <p>1 Q. The doctors said that they --</p> <p>2 rephrase. I'll come back to it.</p> <p>3 After the rechallenge which brought on</p> <p>4 a -- rephrase.</p> <p>5 The rechallenge was positive because</p> <p>6 the diarrhea returned, correct?</p> <p>7 A. "On selectively recommencing only</p> <p>8 olmesartan and oral intake, the diarrhea</p> <p>9 returned," that's what it says.</p> <p>10 Q. That's a positive rechallenge, right?</p> <p>11 A. It's not a selective or controlled</p> <p>12 rechallenge. It's a positive uncontrolled</p> <p>13 rechallenge, I suppose.</p> <p>14 MR. SLATER: Move to strike.</p> <p>15 Q. That's a positive rechallenge,</p> <p>16 correct?</p> <p>17 MR. PARKER: Objection. Asked and</p> <p>18 answered.</p> <p>19 A. It's a positive uncontrolled</p> <p>20 rechallenge.</p> <p>21 MR. SLATER: Move to strike.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. It is a positive rechallenge, correct?</p> <p>24 A. It's not a controlled rechallenge.</p>	<p style="text-align: right;">Page 109</p> <p>1 saying go on.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. That is a positive rechallenge,</p> <p>4 correct?</p> <p>5 A. Both olmesartan and oral intake were</p> <p>6 present, it's a positive uncontrolled</p> <p>7 rechallenge for olmesartan and oral intake.</p> <p>8 MR. SLATER: Move to strike.</p> <p>9 Q. Doctor, if you keep saying</p> <p>10 "uncontrolled" when I don't ask whether it's</p> <p>11 uncontrolled or not, I'm going to call the</p> <p>12 federal judge in charge of this case and ask him</p> <p>13 to instruct you to answer my questions. Okay?</p> <p>14 A. Okay.</p> <p>15 Q. So here you go.</p> <p>16 Is that a positive rechallenge?</p> <p>17 A. It is a positive uncontrolled</p> <p>18 rechallenge.</p> <p>19 Q. Did I ask you if it's uncontrolled?</p> <p>20 A. By leaving out uncontrolled, you're</p> <p>21 implying it's controlled.</p> <p>22 Q. Doctor, Mr. Parker will ask you</p> <p>23 questions at the end of the deposition. I</p> <p>24 didn't ask you if it's controlled or</p>

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<p style="text-align: right;">Page 110</p> <p>1 uncontrolled. Okay? It may matter to you. It 2 doesn't matter to me. So I would appreciate if 3 you would answer my questions instead of trying 4 to insert what you think may be important to 5 support whatever opinions it is that you're 6 casting in this case. 7 MR. PARKER: Objection to your speech, 8 and just ask a question, please. 9 BY MR. SLATER: 10 Q. That is a positive rechallenge, 11 correct? 12 A. It is a positive uncontrolled 13 rechallenge. 14 Q. All right. In the interest of time, 15 I'm going to ask, Doctor, that your entire 16 testimony be stricken and that you be sanctioned 17 for refusing to answer my questions. Okay? 18 What I may do -- you know what? And I'm going 19 to reserve the right during lunch to call the 20 judge and ask him to instruct you on this. 21 A. I'll leave it to you and Mr. Parker to 22 determine if that's within your rights. 23 Q. Just for the record, did I ask you 24 whether it's controlled or uncontrolled? Yes or</p>	<p style="text-align: right;">Page 112</p> <p>1 A. If you include that they kept her on 2 oral intake, it's, again, a positive drug 3 withdrawal. 4 Q. So this is reported in this document 5 that the patient had a positive dechallenge, a 6 positive rechallenge, and then another positive 7 dechallenge, correct? 8 A. We can debate, you know, I believe 9 those are all uncontrolled based on what we've 10 discussed, but with that recognition I'll say 11 yes. 12 Q. The document goes on to state, "A 13 subsequent colonoscopy, performed four months 14 after the initial biopsies, showed 15 microscopically normal appearing small and large 16 intestine with complete resolution of 17 enteropathy-like changes and thickened collagen 18 band." 19 That's what it documents, correct? 20 A. I'd like to see biopsies of the 21 proximal small intestine, since they imply that 22 those are more severe. 23 Q. Look at the next page, Figure 2. And 24 you can compare it to Figure 1. Do you see that</p>
<p style="text-align: right;">Page 111</p> <p>1 no. 2 A. No. 3 Q. It's a yes or no question. 4 A. I said no. 5 Q. Okay. So I'll try it again. Would 6 you try to answer my question directly only with 7 what I ask? 8 MR. PARKER: Just do that. 9 BY MR. SLATER: 10 Q. Would you do that for me? 11 A. Sure. 12 Q. That is a positive rechallenge, 13 correct? 14 A. It is a positive rechallenge. 15 Q. The letter next states, "Her 16 antihypertensive medication was subsequently 17 changed to ramipril and the diarrhea again 18 resolved." 19 That is a dechallenge, correct? 20 A. Making some assumptions, yes. 21 Q. Assuming that they mean to say we took 22 her off the olmesartan and put her on this 23 different condition, that is a positive 24 dechallenge with the olmesartan, correct?</p>	<p style="text-align: right;">Page 113</p> <p>1 in Figure 2 they say that this shows 2 "Improvement in the appearance of histological 3 feature in the proximal small intestine and the 4 colon following withdrawal of the drug"? Do you 5 see that? 6 A. You asked me about the colonoscopy, 7 and I'm pretty certain they could not biopsy the 8 proximal small intestine on colonoscopy. 9 Q. They obviously think they biopsied the 10 proximal small intestine because they're 11 labeling the picture on the left, correct? 12 A. It's not possible. You don't biopsy 13 proximal small intestine on colonoscopy. 14 Q. I understand that. 15 Do you see the picture in Figure 2 on 16 the left, Figure A? 17 A. Sure. The figure legend says proximal 18 small intestine. I, therefore, have to conclude 19 that they feel that was a biopsy of proximal 20 small intestine. You did not ask me about the 21 figure, you were asking me about the sentence. 22 The sentence says colonoscopy. 23 Q. Figure 2 on Page 361 states that 24 illustration A is the proximate small intestine.</p>